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The long-term objective of this Project is to improve the health of New Hampshire women by improving breast cancer screening and detection. To accomplish this, the New Hampshire Mammography Network is implementing a comprehensive database tracking system, which allows us to follow the outcomes of women receiving mammography (either diagnostic or screening) and other breast procedures (biopsy or fine needle aspiration) over time.

The first year of the Project was a development and design year and the second year was an implementation year; the third year has been devoted to additional implementation activities, developing a computerized system for both data collection and to feed data back to participating sites as a first step in assessing whether feedback on performance improves radiologists' diagnostic acumen. The goals for this year, as outlined in the Statement of Work (Proposal page 18) include: 1) ongoing data collection procedures at mammography facilities in the state, including equipping, training and monitoring staff at mammography facilities and equipping and monitoring cancer registrars; 2) conducting data analysis and feedback, including finalizing report formats, generating policies for report handling and providing physicians and facilities with reports at designated intervals.

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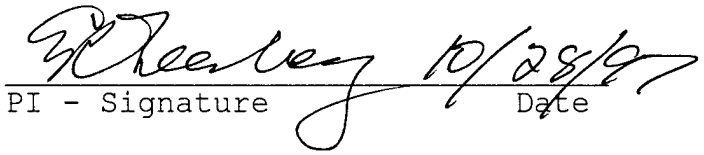

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INTRODUCTION

The long-term objective of this Project is to improve the health of New Hampshire (N.H.) women by improving breast cancer screening and detection. To accomplish this, the New Hampshire Mammography Network is implementing a comprehensive database tracking system, which allows us to follow the outcomes of women receiving mammography (either diagnostic or screening) and other breast procedures (biopsy or fine needle aspiration) over time. We are linking demographic and risk factor information we obtain from women with radiologists' and pathologists' reports. For individuals who are diagnosed with breast cancer, we are linking their data with the NH State Cancer Registry to obtain outcomes through first course of treatment and vital statistics data to match cases with morbidity data.

New Hampshire is well suited to this type of population-based research. It has a stable population with a blend of urban and rural communities and has a relatively high level of literacy (82.2% of New Hampshire adults are high school graduates), which simplifies interviewing and form completion. New Hampshire is also a relatively small state with an estimated population of 1,136,000 (1). Breast cancer is the leading cancer in N.H. women with over 800 cases per year, representing 33% of all female cancers (2). The mortality rate is 29 per 100,000, which is higher than the national rate of 27.3 per 100,000 (3). Women between the ages of 40 and 74 represent about 14% of the population of 160,000 (1). Data from 1991 on the behavioral risk factors of N.H. women revealed that 37% of women between the ages of 40-49 report that they have not had a mammogram within the past two years and 50% of women over age 50 report that they have not had a mammogram within the past year (4). Clearly, the development of a population-based mammography registry is an important contribution to understanding the problem of breast cancer in New Hampshire.

While the first year of the Project was a development and design year and the second year was an implementation year, the third year has been devoted to additional implementation activities, including developing a computerized system for both data collection and to feed data back to participating sites as a first step in assessing whether feedback on performance improves radiologists' diagnostic acumen. The goals for this year, as outlined in the Statement of Work (Proposal page 18), include: 1) ongoing data collection procedures at mammography facilities in the state, including equipping, training and monitoring staff at mammography facilities and equipping and monitoring cancer registrars; 2) conducting data analysis and feedback, including finalizing report formats, generating policies for report handling, and providing physicians and facilities with reports at designated intervals.

We received funding from the Centers for Disease Control in January 1996 to conduct a quality assurance project on the diagnostic acumen of breast pathology. This project has led to the development of two manuscripts currently In Press,

which are included in **Appendix A** (see also NHMN Related Studies Currently in Progress page 13). A proposal for additional funding to assess reproducibility and accuracy of ductal carcinoma in situ grading was developed and an award was received from the Centers for Disease Control and the State of New Hampshire Department of Health and Human Services (see **Appendix A**). This project is currently underway.

We have also been active in the National Cancer Institute Breast Cancer Surveillance Consortium, submitting data collected on mammographic encounters in New Hampshire, and taking the lead in developing a policy and procedure manual to insure data integrity and confidentiality at each Consortium site. The manual is included in **Appendix B**. A manuscript that describes the medico-legal analysis we conducted to insure legal protection of the data at Consortium member sites and the Statistical Coordinating Center (to which all data are sent for pooled analysis) is included in **Appendix C**.

We will address in the Methods and Materials section of this report the progress we have made in accomplishing the above tasks in three sections: ongoing Project Implementation and Start-up; Data Analysis and Feedback Reporting Procedures; and NHMN Related Studies Currently in Progress.

METHODS AND MATERIALS

• Ongoing Project Implementation and Start-up

Our pilot phase came to an end in April 1996. On May 1, 1996, we began implementation with non-pilot sites around the state. **Table 1** (next page) illustrates implementation start dates and status of sites not currently contributing data to the Network. We have distributed all the training materials for mammography facilities and the quality assurance systems for data checking.

Patient, provider and facility identifiers are double-entered by hand and linked using bar code technology and scanning (see **Appendix D** for paper data collection instruments). We are using this technology for assigning data to files and for up-sequencing of multiple visits to one data file so that we can track mammographic occurrences by breast, by woman, by facility, and by radiologists' interpretation(s).

To date a total of 40 (of 46 in the state) mammography facilities have been implemented. Two of the remaining facilities have decided to use computer systems for mammography data collection, which is currently being tested. Two have refused participation by the radiologists. One facility is currently not accredited to perform mammography, and the remaining center is undergoing some staff shortages but expects to join the Project when those are resolved. We hope to have all willing facilities contributing data by the Spring of 1998 (a total of 43 centers).

Table 1 New Hampshire Mammography Network Status
October 15, 1997

Facility	Implementation Date	Type of Data Collection System
A	5/28/96	Paper
B	6/10/96	Paper
C	7/1/96	Paper
D	7/1/96	Paper
E	7/8/96	Paper
F	9/3/96	Paper
G	2/2/97	Paper
H	9/23/96	Paper
I	8/1/96	Paper
J	11/1/96	Computer
K	6/3/96	Paper
L	6/3/96	Paper
M	7/2/96	Paper
N	6/ 24/96	Computer
O	9/16/97	Computer
P	9/23/96	Computer
Q	9/23/96	Computer
R	9/23/96	Computer
S	7/15/96	Paper
T	9/3/96	Paper
U	8/5/97	Computer
V	5/1/96	Paper
W (2 sites)	5/1/96	Paper
X	5/1/96	Paper
Y	11/1/96	Computer
Z (2 sites)	10/8/97	Paper
AA	10/8/97	Paper
BB	10/15/96	Paper
CC	8/5/96	Paper
DD	8/7/96	Paper
EE (3 sites)	9/3/96	Paper
FF	9/3/96	Paper
GG	9/3/96	Paper
HH	1/297	Paper
II	7/2/96	Paper
JJ	9/23/96	Paper
On Hold		
KK	Hold	Awaiting Computer
LL	Hold	Awaiting Computer
MM	Staff shortage - HOLD-per radiologist	Expect Computer
Refusals		
NN	**REFUSED**	
OO	**REFUSED**	
Not Applicable		
PP	**N/A.**	Presently not accredited for mammography.

The four field coordinators hired last year for implementation have completed their work and three have left the project. The remaining field coordinator will provide on-going site support for the duration of the project. We have contracted with Insight™ Mammography Management System, a computerized mammography management system, to customize data entry screens to match our paper forms (see **Appendix E** for Insight™ Contract and sample data entry screens). We will then be able to take data downloads from these sites biannually. Women participants will continue to sign and complete the General Information Form (Study Instruments **Appendix D**), which will be scanned at the Project office.

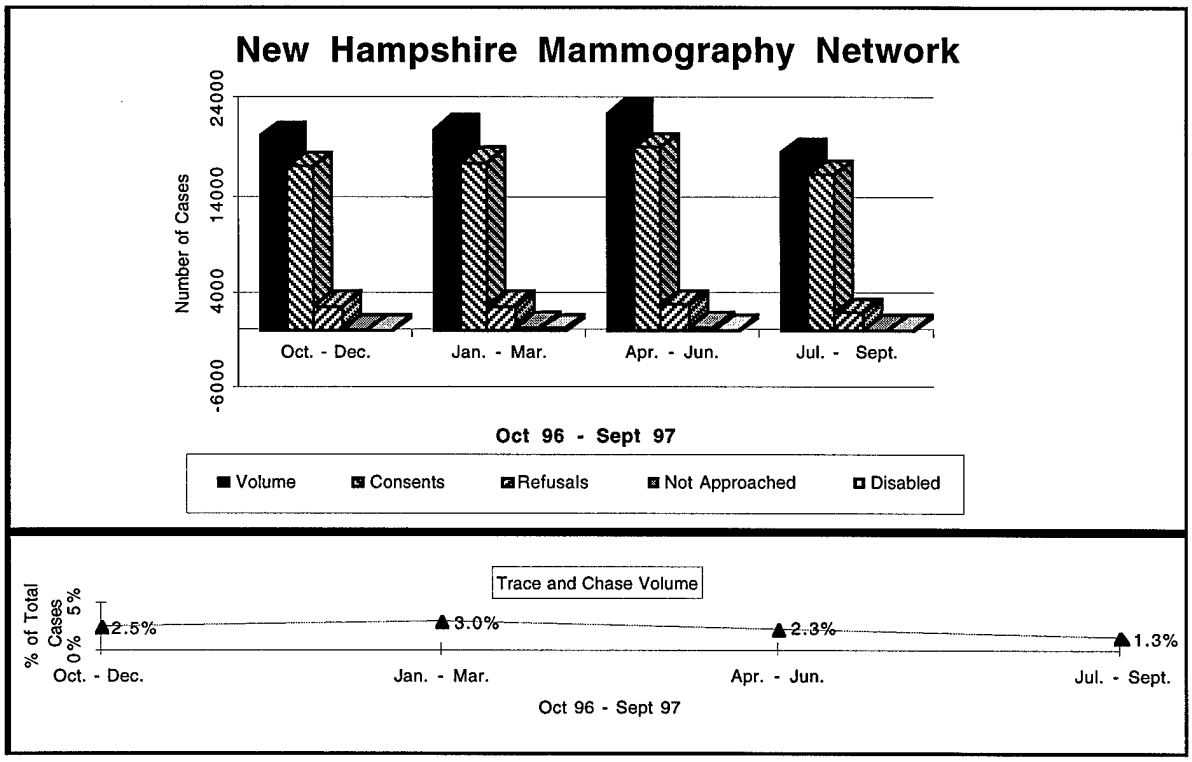
An ongoing goal for Year 3 is to monitor the status of mammography facilities in their contribution of data to the project. Each facility receives a status report at approximately 60-day intervals that reveals the total volume of mammograms done at that facility, the number of women refusing to take part in the project, the number of women not approached due to scheduling or other problems, and the amount of essential information that has not been received from that site with comparisons to the aggregate of other facilities contributing data. These status reports are critical in assisting the facilities in follow-up of missing data and in identifying and correcting problem areas in the process of data collection. **Appendix F** contains a sample status report. Upon receipt of the status reports, facilities are entered into our system for follow-up of missing data (called our "Chase and Trace" System). Forms that are missing essential information are photocopied onto bright pink paper and are returned to the facility for completion or correction. The implementation of this system has resulted in improved completion rates of data forms at the first point of submission.

Figure 2 (next page) outlines the overall volume of mammographic encounters in the database, the refusal rate, the number of disabled individuals who could not take part due to their disability, and the number not approached since the pilot phase ended and actual data entry began (May 1, 1996). From May 1, 1996 through October 15th, 1997, 90,511 mammographic encounters have been entered into the database. The majority of women in the database are over age 50 (55%) and 45% are under age 50. Consent rates have fluctuated on a monthly basis between 88%-96% with a mean of 90%. Those not approached (due to site-specific circumstances and those who are disabled) have reduced dramatically to 1-3%. The follow-up of missing data (Trace and Chase) has ranged from 1.3% - 3%. This missing data is updated in the database when the Trace and Chase reports are returned. All sites but 1 (97.5%) are participating in our follow-up system for missing data. The status reports have been enormously helpful in improving the completeness of data that are submitted to the Project.

Because the accuracy of data is so critical to the research conducted using NHMN data, we have incorporated several quality assurance measures into the process of data collection. First, the scanning technology we are using to process project forms has set parameters for acceptance or rejection of data. For example, if a

woman indicates she has no breast concerns on the Patient Intake Form but goes on to describe a breast lump, the form will be rejected from the scanner for visual inspection and verification. Staff operating the scanner verification have been trained on all parameters for verification.

Figure 2 Volume and Status of the NHMN Database October 1, 1996-Sept. 30, 1997 (current number of facilities = 40).



Second, the patient registration system (where patient identifiers are double-entered) automatically selects cases (10% of cases are selected at random, based on volume of mammographic encounters for each facility) for radiologist report quality assurance. For the selected cases, consent forms are copied and facilities pull the radiologist reports. The field coordinators review the text reports and complete a corresponding radiologist form. These forms are then compared with the reports submitted by the participating radiologists, and discrepancies are reviewed by our radiologist liaison. To date, there is a 96% agreement between the field coordinators' interpretation of the text reports and the completed radiologist reports, indicating that radiologists are completing their forms correctly. Our radiology liaison follows up with any radiologist using an incorrect format in completing data forms.

In our original proposal, we planned to contract with tumor registrars to abstract breast pathology reports at New Hampshire labs. In part because of the funding we received for the N.H. Quality Assurance Project, the labs are sending their pathology reports to our Project office and they are abstracted on-site. Our pathology data entry screens are included in **Appendix G**. Quality assurance is performed by our pathology liaison (a pathologist at Dartmouth-Hitchcock Medical Center) on 20% of the abstracted pathology reports, with greater than 94% agreement between the pathology liaison and the abstractor. Our institutional review board has given us permission to hold identifiers from breast tissue reports for six months, to allow for adequate matching with the NHMN. When this six-month period passes, identifiers are dropped from the pathology database and anonymous data remains. We have developed and tested our matching protocols with the N.H. State Tumor Registry and are able to form the linkages between women in the NHMN and the breast pathology database.

As of October 15, 1023 cases representing 671 women have been matched between the NHMN and the breast pathology database. On the case level, the breakdown of diagnostic categories is as follows: 45 (4%) unsatisfactory cases (repeat biopsy recommended); 665 (65%) benign cases; 53 (5%) atypical cases; seven (1%) suspicious cases; 53 (5%) non-invasive malignant cases; and 200 (20%) invasive malignant cases that match to a mammogram in the registry.

Because our system is currently programmed to generate reports, it is unable to generate aggregate overall data at this time. An addendum data Table will be sent within two weeks that indicates the number of baseline, screening or screening plus additional views linked to pathology outcomes. It will also outline the number of diagnostic, follow-up or additional views to supplement recent exams with appropriate outcomes.

Creation of the database, data management processes (for paper system), and data linking for analyses have all been accomplished. Our further challenges include completing the design and implementation of computer systems for data collection and designing the interfaces between the facilities that use them and our master database. We anticipate having the entire process completed in the spring of 1998 (adjusted from original contract).

- **Data Analysis and Feedback Reporting Procedures**

The second technical objective of our proposal is to evaluate the impact of reporting performance measures on radiologists' diagnostic acumen. The following definitions have been agreed upon by our research team for purposes of conducting these analyses.

1) Screening Mammogram - This is a mammogram whose occurrence is not influenced by concerns about the presence of symptoms, positive clinical breast exam, or prior mammogram one year ago.

2) Positive Screening Mammogram Interpretation - A screening interpretation will be considered positive) if: 1) the American College of Radiology (ACR) Lexicon Code is 0 (assessment incomplete), 4 (suspicious abnormality), or 5 (highly suggestive of malignancy) OR 2) any screening mammogram interpretation (ACR Lexicon Code of 0-5) that is accompanied by recommended follow-up for any additional work-up. In practice settings where the ACR code is determined only by using information beyond the initial screening mammogram, the screening mammogram will be interpreted as ACR code = 0 if there is any additional work-up performed beyond the screening mammogram.

3) Negative Screening Mammogram Interpretation - A screening interpretation will be considered negative if the ACR code is 1 (negative) or 2 (benign finding, negative) AND the recommended follow-up for routine mammogram is one year or longer.

4) Positive/Negative Screening Mammogram Interpretation - A screening interpretation will be considered positive in the first analysis, and then negative in a repeated analysis, if the ACR code is 3 (probably benign finding) AND the recommended follow-up is for less than one year.

5) Cancer Diagnosis - An outcome is defined as cancer (or positive) if there is a histologically proven diagnosis of DCIS or invasive cancer, or registry documentation for cancer within the follow-up period.

6) Non-Cancer Diagnosis - An outcome is defined as non-cancer (or negative) if there is a proved benign diagnosis or no pathology at the end of the follow-up period (one or two years).

7) Follow-up Time - One Year - The one-year analysis will be based on a time period of 12 months from the date of the index mammogram. Twelve months is intended to be a calendar year (e.g., January 1995 - December 1995). The index mammogram is a screening mammogram that begins the follow-up period.

8) Follow-up Time - Two Years - The two-year analysis will be based on a time period of 24 months from the date of the index mammogram. For the two-year analysis, two years would be substituted for one year in the analyses below (Item 10).

9) Accuracy Indicators

a) Positive Screen Mammogram, True Positive (TP), and False Positive (FP) - A positive screening mammogram is a true positive if there is a cancer diagnosis (date of diagnosis will be used for time period indicator) before the end of the follow-up period. This is regardless of the mode of detection. A positive screening mammogram interpretation is a false positive if there is no cancer diagnosis (date of diagnosis will be used for time period indicator) before the end of the follow-up period.

b) Negative Screen Mammogram, True Negative (TN), and False Negative (FN) - A negative screening mammogram interpretation is a true negative if there is no cancer diagnosis before the end of the follow-up period. A negative screening mammogram interpretation is false negative if there is a cancer diagnosis date before the end of the follow-up period.

10) Analyses

a) Screening Interpretation Only - The initial analysis will be for screening mammograms only. In order to include all women in the analysis, women having had additional evaluations at the time of the index mammogram will be included. The mammogram interpretation for these women would be considered as ACR "0" for this analysis.

b) Screening Plus Additional Evaluation Interpretation (Screen-Plus) - The second analysis will be for screening mammography plus further diagnostic work-up. For this analysis, we would use the ACR codes assigned at the end of the complete work-up process, including all radiologic studies up to, but not including, biopsy for all women.

Table 3 illustrates the indices for calculating accuracy.

Table 3 Indices for Calculating Accuracy

Mammography Result	Cancer Status* Positive	Negative	
Mammo +	TP	FP	Total Test +
Mammo -	FN	TN	Total test -
Total	Women with cancer	Women without cancer	

Sensitivity = TP/TP + FN
Specificity = TN/FP + TN
Positive Predictive Value = TP/TP +FP
Negative Predictive Value = TN/FN +TN

* A histologically or registry proved ductal carcinoma in situ or invasive primary cancer of the breast. Lobular carcinoma in situ will be included in one analysis, then removed for a second analysis.

We have developed our report formats, which have been approved by the NHMN Steering Committee (hypothetical reports are included in **Appendix I**). The Steering Committee is composed of members of the research team, community radiologists, community pathologists, and mammography technologists. Any report that contains patient-level information will be treated as confidentially as any medical record (as noted in the Confidentiality Manual included in **Appendix B**). Dummy codes will be generated each time a report is created to protect the identity of a receiving facility or radiologist. These codes will never be able to link radiologist participants to actual study identifiers. We are currently monitoring rates of case outcomes as they are submitted to the NHMN. These issues are outlined in a Report Handling Policy that is also included in **Appendix I.**

Additional Analysis Strategies - In addition to the accuracy indices, a receiver operating characteristic (ROC) curve regression analysis will be conducted. The ROC will be a spin-off of the calculation of sensitivity and specificity, requiring the same definitions. The regression ROC will enable us to compare individual ROC curves while controlling for other variables. We do anticipate that we will have to collect data for a period of at least two years to obtain stable enough rates of sensitivity and specificity at the provider level to conduct the ROC regression analysis. The research team is currently devising the specific methods for conducting these analyses. For these analyses to be conducted accurately, stable estimates of sensitivity and specificity must be present. By January 1998, most sites will have been contributing data for one year. By January 1999, there will be adequate data to determine if reporting has improved diagnostic acumen. Currently reports are produced twice a year. In September, reports are produced which cover the months of January through June. In February, reports are generated for January 1-December 31.

• NHMN Related Studies Currently in Progress

The 1996 New Hampshire Breast Pathology Quality Assurance Study was funded by the State of New Hampshire Department of Health and Health Services through a cooperative agreement with the Centers for Disease Control (contract # 025-090-5659-092-0415-CA). Its purposes were to evaluate the diagnostic accuracy and completeness of information provided in breast surgical pathology reports, and to improve agreement on breast pathology by designing and implementing a standardized breast pathology checklist agreed upon by N.H. pathologists. As previously mentioned, we have included papers describing this project in detail, which are currently In Press in **Appendix A.**

In 1997, we received additional funding from the New Hampshire Division of Public Health Services through a similar cooperative agreement with the Centers for Disease Control (grant # U57-CCU108362-02) to assess reproducibility and accuracy of DCIS grading. This Project is significant because in the past, many pathologists have attempted to describe the different types and patterns of non-invasive carcinomas of ductal origin (DCIS) (5-7). The poorly defined criteria for differentiation of these

patterns have mainly concentrated on the architectural features and the presence or absence of necrosis.

Recently, a classification of DCIS grading (which includes both cytological and architectural features) has been proposed which reflects how the various histological patterns correlate with the mammographic findings and predictive prognosis (8). In this classification, the well-differentiated and poorly-differentiated patterns of DCIS have been found to correlate with low grade and high grade infiltrating tumors, respectively (9). The poorly-differentiated patterns are associated with poor prognostic indicators (p. 53 and C-erb-B2 expression) and a reduced disease-free interval (10). Unless the diagnostic reproducibility of these different DCIS grades amongst every day, practicing pathologists can be determined, the usefulness of such a grading system nationwide will remain unknown and its impact in treatment decisions limited.

As part of the first NH Breast Pathology Quality Assurance Project, we implemented a standardized reporting list, which was voluntarily accepted by participating pathologists. Though we feel this standardized reporting list will assist with an improvement in overall agreement in breast pathology reporting, special attention to specific diagnostic criteria for atypical ductal hyperplasia and ductal carcinoma in situ may further improve the reproducibility of DCIS grading in breast pathology. Our QA project for 1997 intends to assess the reproducibility and accuracy of DCIS grading.

CONCLUSIONS

We have accomplished our goals for the third year of the Project. Our greatest challenges were implementing 40 mammography facilities, insuring that complete and accurate data are collected from all participating sites, and designing a system to automatically produce reports for participating radiologists and mammography facilities. We now have enough data in the registry to develop manuscripts; three have been developed and approved by our steering committee. The first is a comparison of risk factors in women with screen versus interval detected breast cancers. The second examines patient and radiologist factors that influence the probably benign American College of Radiology category. The last involves the outcomes of patients who express breast concerns versus the radiologist's indication for the exam versus the technologist's determination of patient concerns. We have succeeded in obtaining funding for related Projects, with the two breast pathology quality assurance studies, and are confident that the NHMN database will provide an important resource for studies on patterns of care and accuracy in mammography in the coming years.

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NEW HAMPSHIRE MAMMOGRAPHY NETWORK

Annual Report Addendum Tables on ARC Codes Contained in the Database and Amammographic Indication with Linked Breast Pathology Outcomes for Cases Matched to Date

Table 1 American College of Radiology's BIRADS Codes Represented in the database (based on 39,866 cases - those scanned to date)

BIRAD Code	Number % in Database (%)*
ACR O (Needs Additional Assessment)	841 (2)
ACR 1 (Normal)	26,384 (66)
ACR 2 (Negative with Benign Findings)	3,490 (9)
ACR 3 (Probably Benign)	3,724 (9)
ACR 4 (Suspicious of an Abnormality)	748 (2)
ACR 5 (Highly Suggestive of Malignancy)	127 (0.03)

** 2,552 cases are missing this code and are in follow-up system (Trace and Chase)*

Table 2 Mammographic Indication and Breast Pathology Outcomes for Matched Cases in the NHMN and Breast Pathology Databases

Type of Exam	Pathology Outcome	Number of Women ***
Screening*	Suspicious	4
(n=356)	Benign	231
	Atypical	18
	Non-Invasive Malignant	18
	Invasive Malignant	71
	Unsatisfactory	14
Diagnostic**	Suspicious	3
(n=315)	Benign	205
	Atypical	16
	Non-Invasive Malignant	15
	Invasive Malignant	64
	Unsatisfactory	12

* Screening = Screening or Screening Plus Additional Views
** Diagnostic = Diagnostic, Follow-up or Additional Views to Supplement Recent Exam
*** By Screening Category

LIST OF APPENDICES

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G. Pathology Interpretation Database Screens

H. Recent Publication about the National Cancer Institute Breast Cancer Surveillance Consortium, which includes the New Hampshire Mammography Network.

I. Sample Feedback Charts (outcome measures) and Report Handling Policies

APPENDIX A

NHMN/Pathology Project Papers in Press

A Statewide Study of Diagnostic Agreement in Breast Pathology

by

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This study was supported by The Centers for Disease Control to the New Hampshire Division of Health and Human Services (411216), the U.S. Department of Defense (DASD17-94-J-4109), and Public Health Service Grant CA23108.

Abstract

Objective: To assess diagnostic agreement among community-based pathologists without a special interest in breast pathology reading representative breast tissue specimens, and to determine whether diagnostic variability is associated with sample source or slide quality.

Design: Each pathologist evaluated slides from 30 cases randomly selected from a statewide breast pathology database. The diagnostic categories used were: benign, benign with atypia, non-invasive malignant, and invasive malignant.

Setting: Community-based pathology practices in New Hampshire.

Participants: Twenty-six (59%) of the 44 eligible pathologists in the State participated in the slide review.

Main Outcome Measures: Diagnostic agreement was assessed using the kappa coefficient.

Results: Agreement was high among pathologists for determining diagnostic category (kappa = 0.71), and was nearly perfect for benign versus malignant categories (kappa = 0.95). There was less agreement for the categories of non-invasive malignant and benign with atypia (kappa = 0.59 and 0.22, respectively). There was no apparent relationship between levels of diagnostic agreement and tissue source or perceived slide quality.

Conclusions: Diagnostic agreement for breast tissue specimens is high overall among community-based pathologists, but clinically relevant disagreements may occur in the assessment of non-invasive malignant diagnoses. Establishing reread policies for certain diagnostic categories may reduce the possibility that diagnostic misclassification will lead to over- or undertreatment. The high diagnostic reproducibility for malignant lesions of breast suggests that it is unnecessary for a central review of these lesions in national cancer trials.

Introduction

The frequency of diagnosis of breast cancer has increased markedly over the past two decades, particularly for non-invasive ductal carcinoma in situ[1, 2]. Much of this increase results from greater use of mammography and more frequent biopsy of suspicious findings. Previous studies have found relatively poor agreement among pathologists in their diagnostic assessments of breast disease[3, 4], but these studies have largely used pathologists in academic centers with a special interest in breast pathology, and the slides reviewed were from cases with challenging histological features. There is scant information on the reproducibility of diagnoses provided by community-based pathologists[5, 6, 7], and no data have been published from a representative mix of biopsy specimens interpreted by U.S. pathologists. This report describes the degree of inter-observer agreement for breast diagnoses among community pathologists in New Hampshire.

Methods

The study was approved by an institutional committee for the protection of human subjects, and endorsed by the New Hampshire Society of Pathologists. We sent recruitment letters and information detailing the proposed study and met with each of the 44 pathologists in New Hampshire who interpret breast tissue. To be eligible to participate, a pathologist must have been actively practicing surgical pathology in New Hampshire, have regularly evaluated breast tissue, and have reported no plans to retire or relocate within the study period. Each participant returned a signed consent form.

Forty-four pathologists met the criteria for eligibility, and 35 (80%), including 6 from the only academic center in the state, agreed to submit breast pathology reports for all biopsied and excised breast tissue, beginning in January 1996. Data on sample source (e.g., core biopsy, mastectomy) and diagnosis were entered into a central database. Pathologists also provided information on demographic/practice characteristics, usual content of breast pathology reports, and tissue processing methods.

After three months of data collection, the pathology database held information on 502 biopsy specimens. From these reports, we randomly chose 30 cases with diagnoses representative of the distribution of all diagnoses in the database. We asked pathologists who had submitted the selected reports to submit four recuts of a representative slide from the case. The recuts were reviewed (by WAW) to ensure that the same histopathological material was present on each

recut. The slides were masked and organized into four complete sets, each mailed according to a structured rotation schedule so that each pathologist read one set of 30 slides. Of the selected slides, 9 were derived from image-guided core biopsies (stereotactic or ultra-sound guided) and 21 from excisional biopsy and mastectomy specimens.

All participating pathologists used a standard reporting sheet to record their interpretations of each slide in the circulated set. Summarized categories of diagnosis were: benign, benign with atypia, non-invasive malignant and invasive malignant. The pathologists also evaluated each slide for processing, staining and sectioning quality by categories of: excellent, very good, satisfactory, and unsatisfactory. For slides with quality perceived to be less than very good, the participants were asked to detail the deficiency. Possibilities included inadequate tissue fixation, poor tissue processing (alcohol clearing, paraffin infiltration), section artifacts (thickness, wrinkles), and suboptimal staining. Participants were blinded to the original diagnosis and to each others' readings.

To assess diagnostic agreement, we computed a kappa statistic for the overall agreement in all four diagnostic categories, and for comparisons between categories- e.g., benign cases versus malignant categories and non-invasive malignant cases versus all other categories. The kappa statistic estimates the level of agreement, after accounting for agreement that would be expected by chance alone. Kappa statistics less than 0.4 represent fair to poor agreement, values of 0.4 to 0.8 represent moderate to good agreement, and values over 0.8 represent excellent agreement.[8] The impact of slide quality and sample source was also examined in subgroup analyses.

Continuing Medical Education credits were awarded to all pathologists completing the project, and each was sent a report comparing his/her individual interpretations with the statewide aggregate results. The results were presented at the annual meeting of the New Hampshire Society of Pathologists.

Results

Twenty-six (74%) of the 35 pathologists who submitted reports to the database took part in the slide review and contributed data to the current analyses. The characteristics of the 26 participants differed little from those of the 17 eligible non-participating pathologists (**Table I**). Of the nine who did not provide data for the analyses, one (WAW) was ineligible (had viewed the slides during the selection process), three were excluded because they read study slides as a group, and five chose not to participate in this portion of the project.

We received a total of 775 review diagnose. Five forms were left entirely blank, one each by five pathologists. The distribution of diagnoses for the study slides was comparable to the distribution of diagnoses reported to the breast pathology database at the time the random sample of 30 cases was chosen; i.e. for study slides: 489 (63%) benign; 47 (6%) benign with atypia; 66 (9%) non-invasive malignant; and 173 (22%) invasive malignant, and for the database: 330 (66%) benign; 18 (4%) benign with atypia; 28 (6%) non-invasive malignant; 122 (24%) invasive malignant.

There was a clear consensus on the diagnosis for almost every case, with complete agreement for 11 (37%) cases (**Table II**). For differentiation between benign and malignant categories, there was complete agreement in 22 (73%) cases. Clinically significant diagnostic variations were observed in eight (27%) cases (N, O, P, Q, S, T, U, V), with discrepancies in benign versus malignant diagnoses. In two of these cases (N and P), the majority diagnosis was benign with one diagnosis of invasive malignant. In three cases (X, Y, Z), there was substantial disagreement between non-invasive malignant and invasive malignant. In six (20%) cases (H-M), the majority diagnosis was benign, but one pathologist diagnosed benign with atypia.

The kappa coefficient confirmed a high level of agreement over all categories, for individual diagnoses and for the distinction between the two benign versus the two malignant categories (**Table III**). Less reproducible diagnostic categories, compared with others, were the benign with atypia and non-invasive malignant, with kappas of 0.22 and 0.59, respectively. No single pathologist or group was found to disagree with the diagnoses of colleagues more frequently than others.

Only 30% of the participants routinely review core biopsies in their daily practice. However, the kappa coefficient for the 9 image-guided core biopsies was 0.85 overall, and 0.98 for distinguishing between the benign and malignant categories. These figures were only slightly lower for the non-core biopsy specimens (0.60 and 0.85, respectively). Kappa coefficients for distinguishing between diagnoses of non-invasive malignancy versus the other categories were 0.57 and 0.60 for the core and non-core specimens, respectively. The recognition of "special type" tumors (lobular, colloid) in both the core and non-core specimens was excellent.

For slides where reviewers rated the quality lower than very good, the most commonly cited deficiencies were fixation and staining quality. However, reduced quality did not seem to affect diagnostic agreement. The kappa coefficient for slides interpreted as of high quality (rated by ≥75% of participants as excellent, very good, orsatisfactory) was 0.64. For slides classified as unsatisfactory or rated by ≥25% of

reviewers as only satisfactory, the kappa coefficient was 0.69. The twelve pathologists classifying 17 slides as unsatisfactory, attributed the poor quality roughly equally to fixation, staining, sectioning, and processing. No single laboratory was responsible for consistently sub-standard slide quality.

Nineteen of 29 pathologists (66%) completed our survey about breast pathology reread procedures (defined as a second pathologist giving an independent evaluation of all or some breast pathology cases). Of these, 16% reported rereading all breast tissue cases (benign and malignant). An additional 37% reported rereading all malignant , benign with atypia and non-invasive malignant cases. Rereading benign with atypia and non-invasive malignant cases was reported at 21% and 26% respectively.

Discussion

This study indicates a high level of diagnostic agreement for the type of breast pathology material routinely reviewed in practice by community pathologists in New Hampshire. None of these pathologists has a special expertise in breast pathology

There were high kappa coefficients for all four diagnostic categories, but particularly for distinction between the benign and malignant categories, between the invasive malignant category and all other categories and between the benign (without atypia) category and all other categories. This is a higher level of agreement than was reported in a prior study of diagnostic reproducibility of proliferative breast lesions[4]. The slides reviewed in that study were selected to include a high proportion of controversial and difficult borderline lesions; our slides comprised a representative sample of the diagnostic categories seen routinely in practice. The participants in the prior study also used mutually agreed upon diagnostic criteria while our participants followed their individual criteria for diagnosis within a standardized checklist.

Despite the excellent agreement overall, there are situations when anything less than perfect agreement may be clinically unacceptable. A diagnosis of malignancy, when none is present, may result in unnecessary therapy and concern. Similarly, misdiagnosing malignancy as a benign condition would result in needed therapy not being received. In this study, such critical disagreements occurred primarily in the differentiation between diagnoses of benign with atypia and non-invasive malignant. In most institutions, a woman whose breast biopsy diagnosis is benign with atypia receives follow-up surveillance, without treatment; whereas a

non-invasive malignant diagnosis warrants at least surgical excision, and often more extensive treatment.[2] Among the 30 reviewed cases in our study, five of 66 (8%) diagnoses of non-invasive malignant (cases O, Q, S, T, U) represent instances where the consensus opinion of the other pathologists was that no malignancy was present. In seven instances of a non-invasive malignant diagnosis (cases W, X), most pathologists had diagnosed invasive cancer; in two cases (Y, Z), pathologists were approximately equally divided between invasive and non-invasive assessments. There were two instances of a diagnosis of invasive malignant for which the consensus opinion was no malignancy (cases N and P), and one instance of a diagnosis of no malignancy (benign with atypia, case V) where the consensus opinion was that malignancy (non-invasive) was present. Most pathologists in our state have told us they confer with their colleagues in difficult diagnostic breast cases; therefore these disagreements, usually representing the divergent view of one pathologist, would almost certainly have been exposed by a second evaluation. Disagreements might also be reduced through use of standardized diagnostic criteria for the differentiation between benign with atypia and non-invasive malignant categories.[4] Since only 30% of the pathologists in New Hampshire evaluate image-guided core biopsies, the exceptional diagnostic agreement for these specimens throughout the state suggests that fears of a prolonged learning curve for the evaluation of such biopsies by pathologists when a stereotactic or ultrasound-guided service is introduced are unfounded.

Our study is one of few that has focused on the diagnostic reproducibility of routinely practicing pathologists without a special interest or expertise in diagnostic breast pathology. The most comprehensive study evaluating consistency of histopathological reporting was carried out by the United Kingdom National Breast Screening Programme in 1994 and involved up to 251 pathologists reviewing multiple sets of slides over 3 years.[5] As in our study, a high level of diagnostic consistency was achieved for most major categories of breast disease except when distinguishing benign with atypia and non-invasive, malignant categories. However, the slide sets did not represent the routine breast pathology caseload and slide quality was not formally assessed. Bianchi's study showed good overall diagnostic agreement among 12 community-based Italian pathologists with comparable diagnostic discrepancies between benign with atypia and non-invasive malignant.[6] However, although the study did control for the technical quality of the histological sections, the cases selected for review were known to present diagnostic problems rather than randomly-selected cases. Similar conclusions regarding diagnostic consistency were drawn from the study, in 1985, by members of

the Medical Research Council Breast Tumor Pathology Panel in the United Kingdom who evaluated 40 consecutive cases submitted from health districts throughout the United Kingdom[7].

Until more specific differentiating morphometric criteria or a biologic marker are determined, borderline proliferative breast lesions (representing 10% of our pathology database) will continue to be interpreted variably by community-based and expert pathologists alike. The natural history of low-grade non-invasive lesions as compared with the benign but atypical lesions, is poorly understood. If the outcome of future clinical trials is to recommend comparable treatments for these borderline lesions, then the necessity to distinguish reproducibly between them may be alleviated.

Large cooperative clinical trials, such as the National Surgical Adjuvant Breast and Bowel Project (NSABP), have tried to minimize inconsistencies of their pathologic findings by requiring that a central laboratory review all pathologic materials submitted by institutional pathologists.[9] Unless the clinical trials are specifically focusing on known areas of diagnostic variation, this procedure may not be necessary, if the results of our current New Hampshire study apply broadly to pathologists elsewhere.

Two studies have stated that optimal tissue fixation and processing are major factors in improving inter-observer agreement in the histological grading of breast carcinomas.[10, 11]. In our study, reduced slide quality did not appear to affect diagnostic accuracy; indeed, for slides classified as of unsatisfactory interpretive quality or rated by ≥25% as only satisfactory, the kappa coefficient improved from 0.64 to 0.69.

Three potential limitations of this study merit consideration. First, while the participation rate was good (80% of eligible pathologists submitting information to the pathology database and completing some aspects of the study), only 59% completed the slide review portion of the study. Willingness to take part in such a slide review may be considered a potential bias in participant selection and result in increased accuracy and agreement as compared with the community as a whole. Second, a "representative" slide was requested for review, increasing the potential for sampling variability. In routine daily practice, pathologists would evaluate more than one slide from excisional and mastectomy specimens. Third, the uniform reporting form may have influenced final interpretations, since its format discourages wordy comments.

In summary, breast pathology diagnoses among community pathologists in New Hampshire are highly reliable overall, particularly for the benign versus

malignant categories, and for core biopsy specimens and "special type" tumors. Tissue processing and slide quality do not measurably affect diagnostic agreement. Rereading breast pathology cases in categories critically important for determining treatment plans (benign with atypia and non-invasive malignant categories) only occurs about 74 and 69% of the time, respectively. A consistent slide review policy for breast pathology could lessen the likelihood of misclassification error. Clinically relevant diagnostic disagreements still occur, however, among non-invasive malignant diagnoses. The willingness of so many New Hampshire pathologists to participate in this project attests to their continued commitment to address these diagnostic variations and minimize clinically significant disagreements.

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Tables

Table I: Characteristics of Eligible Participating and Non-Participating Pathologists

Characteristic	Eligible Non-Participants (n=17)	Participants (n=26)
Age: median (range)	53 (35-65)	47 (36-65)
Years in practice: median (range)	15 (4-20)	16 (2-37)
% Male	100%	69%

Note: one pathologist (WAW) is excluded from this table (ineligible to participate in slide read, but contributes reports to the database).

Table II: Distribution of Diagnoses (n) by Slide for the 30 Representative Cases

Slide	Benign (n)	Benign with Atypia (n)	Non-Invasive Malignant (n)	Invasive Malignant (n)
A	26	0	0	0
B	26	0	0	0
C	26	0	0	0
D	26	0	0	0
E	26	0	0	0
F	26	0	0	0
G	24	0	0	0
H	25	1	0	0
I	25	1	0	0
J	25	1	0	0
K	25	1	0	0
L	25	1	0	0
M	25	1	0	0
N	24	1	0	1
O	23	1	1	0
P	23	1	0	1
Q	22	3	1	0
R	22	4	0	0
S	19	6	1	0
T	13	12	1	0
U	13	12	1	0
V	0	1	25	0
W	0	0	1	25
X	0	0	6	20
Y	0	0	13	12
Z	0	0	16	10
AA	0	0	0	26
BB	0	0	0	26
CC	0	0	0	26
DD	0	0	0	26

Table III: Kappa Coefficients[1] for Randomly Selected Slides in the Four Diagnostic Categories

Diagnostic Category Comparisons	All Slides (n=30)	Image-Guided Core Biopsies (n=9)	Excisional or Mastectomy Sections (n=21)
Benign vs. Malignant[2]	0.95	0.98	0.94
Benign without Atypia vs. All Other Categories	0.79	0.94	0.73
Benign with Atypia vs. All Other Categories	0.22	0.00[3]	0.21
Non-Invasive Malignant vs. All Other Categories	0.59	0.57	0.60
Invasive Malignant vs. All Other Categories	0.85	0.83	0.85

[1] There were 24 to 26 independent reviews per slide.

[2] $p<0.001$ for all kappas unless otherwise noted.

[3] $p=0.69$—Note that none of the 9 slides had final diagnoses of benign with atypia.

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Can We Improve Breast Pathology Reporting Practices? A Community-Based Breast Pathology Quality Improvement Program In New Hampshire:

by

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ABSTRACT

We implemented a regional quality assurance program in New Hampshire (NH) to evaluate breast pathology practices and attempt to improve the completeness of information provided in breast surgical pathology reports. We also assessed the degree to which NH pathologists agree with National Guidelines. The program's objective was to promote a consistent standard of care for patients whose breast pathology is interpreted in NH. Using a sequential survey technique, we were able to obtain consensus on breast tissue report content that was similar to National Guidelines. We also found that 52% of the reporting elements improved in the post-intervention period, although only one reached statistical significance. In conclusion, pathology interpretation is the "gold standard" for determining both screening effectiveness and subsequent treatment of breast cancer, yet variability in breast tissue reporting exists. It is critical that more research be done to improve breast pathology interpretation and reporting practices.

Key Words: Breast Pathology, Pathology Reporting Practices, Breast Cancer

INTRODUCTION

Research in breast cancer screening and diagnosis has received a great deal of recent attention as the effectiveness of screening mammography in women of various age groups is questioned[1-3]. New Hampshire (NH) is one of ten states currently in the process of developing a population-based mammography registry (New Hampshire Mammography Network)[4]. NH is also a state with a large Centers for Disease Control funded community-based breast and cervical screening program that is supplemented by state funds. In combination, these programs will provide 4,000 free mammograms to underserved women. Such screening programs are proliferating in virtually all states around the country.

Because the pathological diagnosis of a breast lesion is traditionally considered the "gold standard" in evaluating screening effectiveness and determining treatment modalities, follow-up for the registry tracking system and the State screening programs includes obtaining pathology reports on all breast tissue examined and linking these to mammographic interpretations. To evaluate the completeness of breast surgical pathology reports and diagnostic accuracy, we implemented a regional breast pathology quality improvement (QI) program in NH. The objective of the program was to promote a consistent reporting standard and improve breast tissue reporting for patients whose breast pathology is interpreted and reported within the state.

The QI program had two phases. In Phase I we conducted a baseline assessment of current practices in specimen sources, specimen evaluation, slide preparation and pathology reporting in NH hospitals. We additionally established state-wide consensus of diagnostic core variables for breast pathology reports based on nationally established criteria[5, 6] and assessed whether the process of the pathologists' coming to consensus improved subsequent report content. In Phase II we determined the degree of agreement amongst pathologists in the diagnostic assessment of breast tissue. We also explored the degree to which variability in diagnostic interpretation is associated with sample sources, specimen evaluation or slide preparation. The results of Phase II are reported in detail elsewhere[7]. This paper describes the activities undertaken in Phase I.

METHODS

- Physician Recruitment, Survey Development and Implementation

Pathologist eligibility requirements included interpreting breast tissue pathology in a NH practice and not relocating or retiring within the study time period (one year). Because the QI program contained an extensive evaluation component, Institutional Review Board approval was applied for and granted. The QI Study was described in detail in subsequent letters and fact sheets, and informed consent was obtained from all pathologists willing to participate. In addition, the study's

pathology liaison (WAW) visited each pathology lab in the state to discuss the program's objectives personally.

Three surveys were then designed, developed and implemented. One obtained information on the demographic and practice characteristics of pathologists, which was administered after participants' informed consents were received by the Project office. The second survey ascertained specimen sources and methods of preparation and processing by participating laboratories. This was administered to one designated pathologist at each laboratory. The final survey ascertained which diagnostic criteria pathologists felt should routinely appear in a breast pathology report.

The surveying of report content began after pathology report baseline data collection was complete (see below). A sequential surveying technique was utilized to obtain state-wide overall agreement on the content of such reports:

- the initial survey was administered, asking pathologists what components they felt should routinely appear in a breast pathology report, according to sample source and diagnosis;
- data from all surveys were entered and analyzed using descriptive statistics;
- a draft of the results was sent to participating pathologists with a request for feedback;
- pathologists' comments were compiled and the checklist revised;

- the revised checklist was mailed to participating pathologists with another request for their comments;
- when pathologists' comments were no longer substantive, the checklist was finalized and circulated for final approval;
- the final checklist was printed on pocket-size cards and distributed to all pathologists in the state.

• Pathology Report Database Design, Data Entry, and Quality Assurance

As part of the NHMN mammography registry project, the majority of women who obtain mammograms (approximately 90%) at participating facilities (n=36) have agreed to allow access to their breast tissue reports. Institutional Review Board approval was obtained to maintain an anonymous database of breast pathology reports for women who did not consent to take part in the NHMN Project or who received mammograms at facilities not yet taking part in the Project.

At each institution participating in the Breast Pathology QI Project, a designated pathologist or laboratory assistant made copies of all breast tissue reports (including fine needle aspirates) and submitted them, in batched quantities, to the project office. Breast tissue reports were initially collected for a three month period to assess baseline content of breast pathology reports. These were abstracted by MSE and entered into a specially designed relational database.

The database was developed by the study's pathology liaison (WAW) and pathology coordinator (MSE), using the core variables

designated by the National Cancer Institute Sponsored Breast Cancer Surveillance Consortium[8] and other information commonly included in pathology reports in New Hampshire[7]. To maintain confidentiality, no identifying information was included in the database. Each patient, pathologist, and lab was assigned a unique ID used for linking and tracking data.

Data collected in the pathology database included: data links (anonymous and unique patient ID, patient's date of birth and gender); site information (lab code, pathologist code); case information (date of procedure, case number, type of procedure and laterality, history of previous biopsies); and diagnostic information (includes a number of categories for both benign and malignant conditions, as well as prognostic indicators such as Scarff-Bloom-Richardson (SBR) grade and estrogen or progesterone status).

In the initial stages of database design and data collection, information from submitted pathology reports was transcribed onto a standard paper form and reviewed for accuracy by the pathology liaison (WAW) prior to entry into the pathology database. When the format of the database stabilized, a transition was made to entering data directly into the computer from the pathology reports. To evaluate the accuracy of information extraction from the reports and data entry, 20 records from every batch of 100 sequentially entered in the database were randomly selected for review by the pathology liaison (WAW).

Percent agreement between the two observers (MSE and WAW) on the randomly selected records entered to date (n=160) is between 75 and 100% with a mean of 91%. The inconsistencies between the reviewers were minor in every case. Two discrepancies led to further refinement of the database to accommodate additional diagnostic criteria commonly reported in the state. The remaining errors were as follows: lesion size not recorded (n=5); histological subtype recorded incorrectly (n=3); benign microcalcifications excluded (n=2); intraductal papillomatosis recorded as single papilloma (n=1); lymph node counts did not tally (n=1); omitted lobular hyperplasia (n=1); type of invasion recorded incorrectly (n=1).

After the baseline period was complete (study months 1-6) and sequential administration of the report content survey had begun, pathology reports continued to be batched and sent by participating labs throughout the study time period. A continuing medical education session was held in the ninth study month to share the results of the data collected to date, particularly the results of state-wide consensus on breast pathology report content. Results of interpretive agreement from Phase I were also shared [7].

- Assessing Improvements in Breast Pathology Reports

To assess whether breast pathology report content improved as a result of coming to consensus on content, we randomly selected 45 reports of invasive and non-invasive breast cancer based on their

relative distributions in the database in the baseline period and compared them to 45 reports of comparable distribution (invasive/non-invasive) randomly drawn from the database after the sequential surveying technique was implemented. Comparisons were made based on a reporting variable being mentioned as either present or absent in the report versus no mention of relevant variables (either as present or absent) in the baseline versus post survey periods. Descriptive statistics and the McNemer's test of symmetry were used to evaluate improvements in report content.

RESULTS

• Characteristics of Pathologists and Laboratories

The demographic/practice characteristics survey and the report content survey were completed by 91% and 94% of participating pathologists, respectively. The survey on specimen preparation was completed by 83% of designated pathologists, representing the 14 participating labs where breast tissue is processed.

Forty-three pathologists interpret breast pathology in New Hampshire and were eligible to take part in the Project. Of these, 35 (79%) agreed to participate. Seventeen of the state's 26 hospitals have laboratories where breast specimens are grossed in and read; 14 (82%) agreed to take part. Ten hospitals have labs that cut slides; 8 (80%) took part.

Project participants ranged in age from 31 to 60 with a mean age of 47 (S.D.=8.0 years). The majority were male (72%). The mean year of graduation from medical school was 1976 with a range between 1958 and 1989. The mean year for completion of residency programs was 1981 with a range between 1963 and 1994. Thirty six percent of participating pathologists underwent fellowship training and completed this training between 1982 and 1995. Ninety-seven percent were Board certified in pathology. Pathologists had been practicing at their current laboratory locations for between 3 months and 33 years with a mean of nine years (S.D.=8.2 years). Pathologists had been interpreting breast pathology for 2 - 37 years with a mean of 14 years (S.D.=8.7 years). Lastly, they participated in 15 - 191 hours of continuing medical education in pathology over the past year, with a mean of 76 hours (S.D.=46 hours); this broad range is due to the mix of academic and community pathologists in the state.

The fourteen pathology laboratories reported reading between 700 and 17,280 pathology cases per year (mean=5,241, S.D.=3,820). Of these, between 20 and 720 cases per year are breast tissue (mean=258, S.D.=183). Ninety-three percent of sites evaluate fine needle aspirations at an annual volume of between 10 and 224 cases (mean=74, S.D.=63), and 29% reported evaluating stereotactic-guided core biopsies at an annual volume of between 5 and 104 cases (mean=70, S.D.=46).

At 64% of the labs, breast biopsies resulting from clinically detected masses or abnormal mammograms were always received in

the fresh state from the operating room. In the remaining cases they were sometimes received fixed in formalin. A frozen section was performed on between 3 and 50% (mean 20% S.D.= 16%) of labs' breast biopsies. In 50% of labs, mammographic x-rays always accompanied excisional and/or needle localization specimens from the operating room, and 93% of pathologists found these accompanying films useful. In 86% of laboratories, specimen radiography was performed, and of these 8% were done in pathology and 92% were done in radiology.

At 93% of pathology labs in New Hampshire, excisional and/or needle localization specimens were always inked. For 71% of labs, fresh tissue (if present in adequate quantities) was submitted for biochemical assays for estrogen receptor and progesterone receptor status in all cases of malignancy; all of these sites use out-of-state labs for ER/PR. If diagnostic tissue was found to be limited, immunohistochemical studies for estrogen and progesterone receptivity were performed on paraffin-embedded blocks by all labs in all cases of malignancy. Twenty-one percent performed the immunohistochemical assays on-site; the remainder were sent to commercial labs. Forty-three percent of labs performed cell cycle analysis by flow cytometry in all cases of malignancy. Of these, 21% performed this on-site with 36% performing this on fresh tissue and 57% performing it on paraffin-embedded tissue blocks.

- <u>Opinions about Breast Tissue Report Content</u>

All pathologists agreed that the presence of microcalcifications and epithelial hyperplasia (with and without atypia) should be mentioned in breast reports for benign disease. Ninety-three percent felt that biopsy size should be included, but few felt that information in the report regarding risk for development of subsequent cancer or follow-up recommendations was required (35% and 24% respectively).

Table 1 outlines the proportion of NH pathologists who advocate certain core diagnostic variables in breast pathology reports for non-invasive and invasive carcinoma; these are compared to the recommendations of the Association of Directors of Anatomic and Surgical Pathology (ADASP)[5, 6]. **INSERT TABLE 1 ABOUT HERE.** Here the range of recommended core diagnostic variables is 10-100% with biopsy and lesion size, whether it was discrete or multifocal, the in-situ pattern, presence of microcalcifications, margin status, and nipple involvement being advocated by more than 90% of pathologists for non-invasive carcinomas. Recommendations regarding prognostic risk or follow-up are advocated by only 14% of pathologists. Similar findings are noted for reporting on invasive carcinoma, though tumor histological type, tumor grade, and presence of associated extensive in-situ pattern, angiolymphatic and perineural invasion, and axillary lymph node dissections are additionally advocated by 100% of NH pathologists.

- Actual Performance on Content of Breast Tissue Reports

Table 2 illustrates our pre-post assessment of breast tissue reporting for invasive and non-invasive breast carcinoma. **INSERT TABLE 2 ABOUT HERE** The variables in this table represent the core diagnostic variables participating NH pathologists agreed upon as part of the survey sequencing process. Here the range of core diagnostic variables reported in the baseline period range from 0-100, with size of excised specimen and laterality of the breast being the only core variables actually being reported on in more than 90% of the reports selected. The range is the same in the post sequencing survey period. Type of procedure done and resection margin status were reported in 89% of the reports in the post survey period

Table 2 also indicates that more than half (52%) of the core diagnostic variables evaluated improved in the post survey period compared to baseline (those bolded in Table 2). However, only reporting on the extent of associated in-situ component was found to be statistically significant ($p \leq 0.01$). Four report elements remained unchanged, and six were actually reported less often in the post survey period than they had been at baseline.

DISCUSSION

We observed high levels of interest in our breast pathology QI project by NH pathologists and laboratories, as indicated by our high response rates (79% and 82% respectively). Clearly this is an important issue for pathologists in the state. Our study revealed that NH

pathologists are well trained and experienced, all completing a residency training program and nearly all being Board certified. In the last 15 years, 35% of the pathologists had acquired additional Fellowship training. As well as evaluating routine surgical excisional biopsies, including needle localization specimens, diagnoses were made on stereotactic- and ultrasound-guided core biopsies and fine needle aspirations.

We also learned that a great deal of variability exists in the volumes of breast pathology interpreted in NH laboratories. Only one participating laboratory was based in an academic medical center; the others were small to medium sized community-based hospitals in a mix of urban and rural areas. We found essentially no commercial laboratories are used to process breast tissue (hospitals in one region of the state use an independent local laboratory), except to determine estrogen/progesterone status and to perform immunohistochemical assays.

The procedures undertaken to process specimens vary somewhat. The concentration of formalin used for tissue fixation, the time of fixation, sectioning thickness, and tissue staining characteristics are the most variable criteria amongst different laboratories and if substandard, can cause interpretive variations in diagnosis. However, the results of Phase II of this project indicate that within NH, there was no appreciable variability in diagnostic interpretation associated with sample sources or slide preparation[7].

The College of American Pathologists (CAP) provides regular surveys (Q-probe studies) which are designed to measure service quality in individual laboratories as compared to the performance of other participating institutions across the country. The results of a recent Q-probe study (95-03) analyzed how many pathologists are already standardizing the processing of their specimens and the diagnostic and prognostic information detailed in their surgical pathology reports[9]. Four hundred and thirty-four pathology laboratories participated in the study nationwide. The variability was marked. Most participants (65.7%) admitted that they do not use standardized checklists to report core diagnostic variables. The handling of breast biopsy specimens was greatly influenced by how the tissue was received in the laboratory (fresh or fixed), the clinical information provided, and the presence or abscence of a radiograph. Overall, breast biopsy specimen handling in NH fell at about the 70th percentile relative to the performance of the other participating institutions in this Q-probe.

Recently, the Association of Directors of Anatomic and Surgical Pathology (ADASP) published recommendations regarding core variable diagnostic features that should be included in all surgical reports for breast carcinoma[5]. A standardized approach to the gross evaluation and tissue processing of breast excision specimens has also been detailed[6, 10]. The recommendations were intended as an educational resource rather than a compulsory requirement, but it was

hoped that the suggestions would lead to more standardized information being provided to clinicians for them to better evaluate prognostic predictors, disease staging and therapy.

Interestingly, the information that clinical physicians (radiation oncologists, surgeons, oncologists and radiologists) regularly sought on breast pathology reports was also evaluated in the 1995 CAP Q-probe (95-03). Between 76 and 95% of clinical physicians desired that diagnostic and prognostic criteria similar to those detailed by the ADASP be included routinely in all breast carcinoma pathology reports as necessary factors in evaluating optimal patient care. The main concluding recommendation of the study was that a checklist of diagnostic core variables, approved by both the pathologist and the involved physicians, should be included in breast pathology reports.

We were pleased to achieve consensus with participating pathologists on the core diagnostic variables that should be present when a breast cancer (either invasive or non-invasive) is diagnosed and that overall NH pathologists are in agreement with ADASP guidelines. We were also pleased to show improvements in more than half the reporting elements under study; however, we were disappointed that statistical improvement was only noted in one of the reporting elements agreed upon.

Several areas warrent further study and discussion. First, the resources available to conduct the report content assessment were minimal. A total of 90 reports, 45 in the baseline period and 45 in the

post sequencing survey period could only have provided enough power to detect a large effect size. A larger sample size may have identified statistical differences in report content between the two time periods. This is certainly an area for future study.

Second, we suspect that there are characteristics of pathology specimens that promote reporting the absence or presence of certain features, which may have affected our findings. We also suspect that it may be much easier for a pathologist to be prompted by the presence of a diagnostic variable during interpretation and reporting than it is to report the absence of that same variable, regardless of its significance. As part of our project, we developed laminated pocket-sized cards with the agreed upon core diagnostic variables listed. We hoped that the cards would assist in prompting the pathologists to be more consistent in their reporting; this appears not to be the case. Most NH pathologists very likely do not specialize in breast tissue interpretation and the process of using or not using these cues to action based on the variety of tissue being interpreted could effect the impact of such an intervention. Certainly, more research is needed to understand factors that influence breast tissue reporting.

We noted that providing information on the text report for prognostic risk and making follow-up recommendations was only advocated by between 10 - 14% of NH pathologists. Though we expect that many pathologists would agree that noting prognostic risk as well as follow up recommendations in their reports would be useful, these

factors are likely best determined collaboratively by the pathologist, surgeon, radiologist and oncologist. Risk and recommendations are always discussed at length in settings such as the weekly tumor boards where subsequent treatment plans are discussed. We feel this may have influenced pathologists' not advocating these variables in their reports.

The pathologist's text report provides the basis for critical public health and cancer treatment decisions. More consistency is needed on breast tissue reporting than we were able to achieve in our study. This is an immense area for further study. Public health programs that study the effectiveness of mammography and/or that offer mammography screening services should implement quality assurance programs to monitor and attempt to reduce variability noted in pathology interpretation and reporting practices.

ACKNOWLEDGMENTS

The authors gratefully acknowledge the enthusiastic support of the participating New Hampshire pathologists and the N.H. Society of Pathologists. We also extend our sincerest appreciation to Julie Wade for editorial assistance; Brenda Berube for her administrative expertise in assisting with this study; and Margaret Murphy at the New Hampshire Division of Public Health Services for her assistance in obtaining funding.

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Table 1 Percent of NH Pathologists who Feel These Core Diagnostic Variables Should be Routinely Included in all Breast Pathology Reports for Non-Invasive and Invasive Carcinoma, and ADASP Recommendations

VARIABLES	% Say Report in Non-Invasive Carcinoma	% Say Report Invasive Carcinoma	ADASP Recommends
GROSS DESCRIPTION:			
Biopsy size	100	100	yes
MICROSCOPIC DESCRIPTION:			
Lesion size	90	93	yes
Maximum diameter (cm)	83	76	at least
Two dimensions (....x....cm)	35	41	*
Three dimensions (....x....x....cm)	55	62	preferred
Tumor histological subtype	--	100	yes
Tumor grade (e.g.: Scarff-Bloom-Richardson)	--	100	yes
Discrete or multifocal	100	100	*
Presence of associated extensive in-situ component	--	100	yes
Estimation of % of the total tumor size	--	76	*
In-situ pattern	100	--	yes
Presence of Microcalcifications	97	--	mammo correlation
Benign association	52	69	
Malignant association	62	72	
Reserction Margin (RM) status	100	--	yes
Involvement by infiltrating carcinoma	--	100	yes
Involvement by in-situ carcinoma	--	97	yes
Distance between tumor and closest RM	76	--	yes
Involvement of dermal lymphatics	--	93	*
Axillary LN dissections (positive vs. negative)	--	100	yes
Angiolymphatic and perineural invasion	--	100	yes (perineural optional)
Involvement or not of nipple (Paget's)	93	--	yes
Correlation with previous biopsies	--	93	*
ER/PR status	72	--	optional
Biochemical assay	62	72	optional
Immunohistochemical evaluation	83	100	optional
Flow cytometric cell cycle analysis	35	45	optional
TNM classification	--	69	optional
Specification of different components of FCD	76	69	ADH, papillomas
Presence of a mononuclear cell infiltrate	--	31	*
Presence of necrosis	--	83	*
Recommendations regarding prognostic risk	14	--	*
Recommendations regarding follow-up	14	10	*

* Not addressed by the ADASP
-- Not relevant for that category or not asked on subsequent surveys

Table 2 Assessment of Breast Tissue Reporting for Invasive and Non-Invasive Breast Carcinoma at Baseline and Post Sequencing Survey

VARIABLES	% at Baseline	% at Post Sequencing Survey	p value
GROSS DESCRIPTION:	n=45	n=45	
• All resection margins inked	56	41	0.18
• Biopsy size	93	100	--
• Laterality of breast	100	100	--
• Procedure done	80	89	0.29
MICROSCOPIC DESCRIPTION:			
• Tumor size: Max. diameter	72	78	0.60
• Tumor grade (e.g. Scarff-Bloom-Richardson)	79	79	1.00
• Associated in-situ component:	73	73	1.00
a) Extensive/Not extensive	50	88	0.01*
b) Pattern(s)	4	0	--
• Microcalcifications			
Benign/Malignant association	22	42	0.60
• Resection Margin (RM) status	78	89	0.25
Involvement by invasive/non-invasive Ca	16	16	1.00
Distance from closest RM (not for lobular Ca)	71	42	0.16
• ER/PR status: Immunohistochemical/Biochemical	47	36	0.32
To be mentioned, if present:			
Axillary Lymph Nodes (positive Vs negative)	27	36	0.48
Angiolymphatic (incl. dermal) and perineural invasion	54	66	0.71
Involvement of nipple (Paget's)	60	80	0.56
Correlation with previous biopsies/ cytology specimens	31	38	0.53
NON-INVASIVE ONLY:			
• In-situ pattern(s)	40	29	0.89
• Discrete or multifocal	0	2	--
• Nuclear Grade	0	0	--
• No Invasion Seen	2	4	--
OPTIONAL INCLUSIONS:			
• Flow cytometric cell cycle analysis	11	8	0.71
• TNM classification	24	13	0.29
• Specification of different FCD components	32	35	0.82

APPENDIX B

Confidentiality Policy and Manual

CONFIDENTIALITY POLICIES AND PROCEDURES FOR DATA MANAGEMENT

NATIONAL CANCER INSTITUTE
BREAST CANCER SURVEILLANCE CONSORTIUM

12/12/96

Submitted by

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University of Vermont

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We would like to acknowledge with great appreciation The University of Iowa and the University of California, San Francisco for the materials they shared, which contributed greatly to the development of this document.

I. PURPOSE

This policy: 1) defines the types of confidential information collected, stored, utilized and transferred by National Cancer Institute Breast Cancer Surveillance Consortium members ; 2) outlines a minimal set of procedures for safeguarding this information; and 3) proposes an assignment of responsibilities within each contributing institution for these activities. The issue of protecting confidentiality in the use of patient and provider data is becoming increasingly more important as avenues for access, especially via computer, expand. The purpose of this policy is to provide a guide to Consortium members in data handling and use for maintaining confidentiality.

II. BACKGROUND

The three major purposes of the National Cancer Institute Breast Cancer Surveillance Consortium are to 1) enhance our understanding of the operation and conduct of breast cancer screening in the United States, in part to respond to a congressional mandate in the Mammography Quality Standards Act (MQSA); 2) foster collaborative research among participants of the Surveillance Consortium to further our understanding of breast cancer screening; and 3) provide a foundation for the conduct of research, especially basic biological mechanistic research, aimed at improving our understanding of the natural history of breast cancer.

To achieve this purpose, each Consortium member site has established or is in the process of establishing a computerized registry of designated mammographic facilities within a specific geographic region. These registries have established or will establish linkage to the regional population-based cancer incidence registries or local cancer registry in order to assess various screening or diagnostic outcomes, such as the proportion of mammographic examinations that are abnormal, predictive value of mammography, and tests associated with follow-up of abnormal mammographic results in the community. Each Consortium member site collects, stores, utilizes, and transfers confidential data on mammography patients, physician's radiologic reports, and follow-up information, including pathology. These include clinical and epidemiologic data that are routinely collected on patients receiving mammography. These data are collected and may be used in collaboration with other investigators who may or may not be other Consortium members. The National Cancer Institute has funded a Statistical Coordinating Center, to which each site will be sending data for shared and pooled analyses. The term "Registry" will be used below to refer to any NCI Breast Cancer Surveillance Consortium member site.

III. DEFINITION OF CONFIDENTIAL INFORMATION

Confidential information is information that contains identifying data, linking it to a specific research participant: patient, physician, or mammography practice. Such

identifying information includes, but is not limited to: patient, physician or facility name, address, telephone number, social security number, zip code, and/or occupation and employer. Confidential information also encompasses Registry proprietary information which includes, but is not limited to: copyrightable/patentable materials developed by Registry employees, consultants, and/or contractors.

Information generated by the Registry is classified into three categories based on the repercussions which may occur from unauthorized disclosure. These categories and their definitions are:

A. Public Information is information or data collected, compiled, utilized, or generated which is intended for public distribution and use or which may be obtained under freedom of information legislation. Generally, this includes aggregated data in published form, such as articles in medical journals about mammography patterns of care, accuracy, and other related topics. This does not include confidential information.

B. Internal Information is information or data collected, compiled, utilized, or generated by the organization which may be shared with employees and authorized consultants and contractors only. Authorization for external distribution or access shall be obtained from the Principal Investigator. Examples of internal information include mailing lists and technical proposals or software manuals.

C. Restricted Information is confidential information collected, complied, utilized, and/or stored by the organization which contains identifying links with specific individuals or medical practices such as name, address, or social security number. Confidential mammography registry data and reports fall within this category, as do any personal identifiers collected as part of Registry. Proprietary data or information produced by employees, consultants and/or contractors also falls within this category.

The Registry considers all data and information confidential that identify information specific to the patient, physician or facility specific information. Information that characterizes the case load of a specific institution or health care professional is considered proprietary and confidential.

IV. THE RESPONSIBILITIES OF THE REGISTRY

The Registry's intent is to balance its research endeavors with its commitment to protect confidential information obtained and generated in the course of that research. It is the Registry's policy to adhere to laws and regulations that govern the collection, compilation, use, transfer, and storage of confidential data; to protect this information from unauthorized access or use at all time; to assure that this

information will only be transferred, utilized, and/or stored in sanctioned and approved ways; to assure that breaches of this policy are reported promptly and that appropriate corrective and/or disciplinary measures are taken; and to respond promptly to inquires from concerned participants regarding the Registry's research and other activities.

It is the responsibility of the Registry to protect the data from unauthorized access and release. The Registry maintains the same standards of confidentiality as customarily apply to the physician-patient relationship as well as the confidentiality of medical records. This obligation extends indefinitely, even after the patient is deceased or the physician ceases practicing within the area.

The costs of inappropriate release of confidential data are many. Inappropriate release of data could damage an individual whose diagnosis of cancer is made public; facilities and physicians could be severely compromised if accuracy or practice pattern data are disclosed. Legal protection of the data from discovery is necessary to assure that no harm comes to people contributing to the database.

- Government Regulations

Collection, access, use, and disclosure of confidential data pertaining to study subjects entered into the Registry and to proprietary information is governed by federal and state statutes and regulations. The Registry seeks to comply with these laws to the fullest extent possible to meet its obligations to funding sources and to meet its commitment to ethical principles upon which human subjects regulations are predicated.

1. State/Institutional Protection

Individual states may or may not have legislation in place that can provide protection from litigation to databases used for research purposes. If your state has this form of legislation, exploring whether the legislation has been tested in court will give you an indication of how advantageous it is likely to be in protecting research subjects. Quality assurance (QA) statutes have been used for years to protect participants contributing data to sensitive research projects. These institutional statutes are not as protective as they once were due to overuse. Because so many QA statutes have been overturned in court, they generally provide very little protection to databases or research subjects.

List and describe here all state laws, regulations and certificates pertaining to the registry:

---

2. The Federal Certificate of Confidentiality

The Breast Cancer Surveillance Consortium Members have applied for and received Federal Certificates of Confidentiality in accordance with the provisions of section 301(d) of the Public Health Service Act (42 U.S.C. 241 (d)). This certificate is issued to protect the privacy of research subjects by withholding their identities from all persons not connected with the research (See your site's certificate for the conditions that apply to the certificate).

3. Committees for the Protection of Human Subjects (CPHS)
Federal regulations guide institutional committees for the protection of human subjects. However, these regulations have various interpretations, depending on institution. Access to medical records via informed consent is becoming an increasingly controversial issue for institutional review boards. Working closely with your institution's CPHS in describing your project and ALL research subjects involved (providers as well as patients) will assist with compliance to these regulations and with the greatest level of protection by clearly identifying the research subjects.

V. ACCESS TO THE DATA

- Registry Staff Members

Each staff member is required to read this Confidentiality Policy and Procedures Manual and signs a pledge to uphold this policy. The pledge remains in effect after cessation of employment. The Registry secretary (or personnel department) maintains a historical file of staff members who have signed pledges (See Appendix A for sample confidential agreement). The orientation and training of each new staff member shall include instructions concerning the confidentiality of data.

- Non-Registry Investigators and Other Interested Parties

Investigators or public health officials may request access to confidential or aggregate registry data. All requests shall be made in writing and approved by the Principal Investigator or an advisory body (such as a steering committee made up of community radiologists/pathologists and members of the Registry's research team). All procedures shall be followed and documented. All persons given access to data shall read the Confidentiality Policy and Procedures Manual and sign an agreement to adhere to the same confidentiality standards practiced by registry staff members. A formal data request form will be used for every request (See Appendix B for sample request form).

If an advisory committee is used, describe how the committee members are chosen or elected, their length of term and the procedures used to approve a request, including criteria; majority, unanimous, quorum etc.; time from request to approval; notification (See Appendix C for Sample Advisory Committee Operations Policy).
For data involving individual identifiers, requests shall be approved by an

approved Institutional Review Board (IRB) prior to submission of the request to the Registry.

Requests requiring the use of personal identifiers should indicate precautions for providing the necessary confidentiality in accordance with IRB standards, which includes reporting patient, practitioner and facility data in sufficient aggregate to minimize the risk of identifying individuals or individual practices. Any cells that have a small number of cases (which may identify an individual or a facility) shall be suppressed in those reports.

All requests shall clearly state the limits of data use. Data may only be used for the exact purpose for which they are requested. Data shall be kept confidential in the custody of the fewest individuals possible.

Data may only be released to the public for the purpose specified in the request. When data analyses are complete, data shall either be destroyed or, if needed for later reference, maintained in locked storage in the custody of an applicant for a specified period until they are no longer needed. Applicants shall specify the exact time period in their request during which they will require access to data.

All applicants shall agree to make a copy of any proposed publication or other form of public disclosure available to the registry 30 days prior to any public disclosure of data released from the registry. This will ensure adequate time to review, comment or decide to reanalyze and provide a response or alternate explanation, if necessary.

NOTE: FAILURE TO ABIDE BY TERMS OF THE AGREED USE OF DATA MAKES THE APPLICANT LIABLE FOR LITIGATION.

VI. INAPPROPRIATE USES OF CONFIDENTIAL INFORMATION

Confidential data shall never be made available, to the extent allowed by law, for uses such as the following:

- Businesses that desire to market a product to patients.
- Health care institutions, their employees or providers that want to advertise or identify new patients for recruitment.
- Insurance companies that are attempting to determine the status of an individual.

VII. DATA SECURITY

- General Data Management

The following components may be required to assure data security in all areas of Registry operation.

The Registry Director is ultimately responsible for data security.

Suitable locks are installed to control access to the Registry. Custodial staff are notified of the importance of maintaining a secure environment. A roster of persons authorized to enter the Registry is maintained by the Registry Administrative Personnel.

Registry staff are responsible for the confidentiality of all data encountered during data collection.

Confidential data shall not be transmitted from the Registry by any means (mail, telephone, electronic, or facsimile) without explicit authority from the Registry Director or a staff member to whom such authority has been delegated.

A registry-developed mail tracking system may be used to protect confidential data.

Precautions are taken for both physical and electronic security of confidential data sent on magnetic or electronic media.

Secure telephone data transmission includes using an unlisted telephone number, password access to the bulletin board systems, and restricted use of facsimile protect confidential data transmissions.

The physical security of confidential data stored on paper documents, computer printouts, microfiche and other media present in the Registry is ensured.

Confidential documents to be destroyed are kept in a secure environment until they are retrieved by a designated person or vendor for shredding and disposal.

- Report Handling

1. Physicians and Facilities Contributing Data to the Registry
For facilities that provide quality assurance data to contributing facilities/physicians, all physicians can receive reports on their own patients as per agreement with the Registry. These reports may contain identifying information indicating the radiologist or facility. Any report that contains patient level information shall be treated as confidentially as any medical record. For example, dummy codes can be generated each time a report is created to protect the identity of a receiving facility or radiologist. These codes shall never be able to link participants to actual study identifiers. Sites may also use a two step process for generating reports, where two individuals are responsible for report handling within a site, one will be kept blind to the dummy code, but will have access to the database for report production and one will be kept blind to the data source, but will apply the dummy code for processing and ultimate mailing. In generating reports requiring the use of personal identifiers, precautions for providing the necessary confidentiality in accordance

with IRB standards shall be undertaken. This includes reporting practitioner and/or patient data in sufficient aggregate to minimize the risk of identifying individuals or individual practice groups. Thus, any cells that have a small number of cases (which may identify an individual or a facility) shall be suppressed in those reports. Allowable uses of the report shall be clearly printed on the report or accompanying information. All requests for quality assurance data from other persons within the mammography facility shall have written approval from the physician or his/her designate physician in charge of quality assurance at said facility.

2. Contractor and Consultant Access
For those facilities who contract with computer programmers, biostatisticians etc., contractors and consultants who have access to restricted information shall read the Confidentiality Policy and Procedures Manual and sign a confidentiality agreement with assurances that they will safeguard such information from unauthorized access or further disclosure.

3. Statistical Coordinating Center (SCC)
A subset of the data collected at the Registry is transferred to the SCC of the National Cancer Institute's Breast Cancer Surveillance Consortium, located in Seattle, Washington. The data so transferred shall include no personal identifiers. As a member of the Breast Cancer Surveillance Consortium, the SCC has the same standards of confidentiality as all the member Registries.

- Procedure for Release of Data

Confidential data shall not be transmitted from the Registry by any means (mail, telephone, electronic, or facsimile) without explicit authority from the Principal Investigator or a staff member to whom such authority has been delegated. The specifics of the data (i.e. variables, date range) and to whom it will be transmitted shall be clearly communicated in writing to staff.

VIII. COMPUTER SECURITY

Computers should be located in a locked facility which does not have public traffic. Computer security safeguards include the following:

Patient identifiers and demographic information are stored in files that have no other information. Other data are stored in separate computer files in the database. They are linked by a scrambled code that only authorized personnel understand.

There shall be password protection to enter Registry computers, applications and databases. All users accessing the database shall have a unique identification code and password. Passwords are changed on a regular basis or may be inactivated

if the users have not accessed them within a three month period. In this case, the individual would need to be reinstated to regain access to the databases. A user's identification and password shall be invalidated when the individual no longer requires access to the database.

All participating facilities and providers are given a confidential code number that is used in the database. A different confidential code number is assigned when reporting quality assurance data. This number is only known by appropriate staff, the facility and each individual provider.

Security standards strictly control access to the database files; staff have specific authorizations to read, write, erase or modify processed information.

Two copies of the daily backup shall be created. One back-up disk shall be stored in a locked file. The second backup disk shall be stored off site by an approved staff person. New staff shall be asked to store off-site backup disks after the probation period has ended. Registry backup disks should have no identification on them other than a number or code and a generic office address label. Caution will be taken to protect disks when off site by knowing where they are at all times and never leaving them in an unsecured location.

All word processing files that contain codes, passwords, data dictionaries or any descriptions of how to interpret the data should be stored in password protected files or removed from computers, copied onto disks/tapes and stored in locked cabinets.

An in-house printer should be used for the printing of confidential data, and the data never be left unattended in the printer.

Telephone data transmission are secured using an unlisted telephone number.

The use of personal and notebook computers for the ascertainment and management of confidential data is controlled by the same electronic and physical measures as described above to protect the security of the data.

Training and demonstration of computer systems are done with separate fictitious and/or anonymous data sets.

All disks/tapes containing Registry data shall be erased when not actively used for backup or transmitting of data.

- **Protection of Data and Network Connections at the SCC.**

1) Subject ID Encryption - All study identifiers at the site shall be recoded to a new SCC study identifier. To perform the recode, the SCC shall distribute a program based on a published algorithm (Meux, E Encrypting personal identifiers, Hlth Srvcs Res 1994, 29:247-256). The new SCC identifier cannot be reverse engineered to yield

the original identifier. The algorithm shall be used to recode subject identifiers, radiologist identifiers, and radiology site identifiers. Only encrypted identifiers shall ever be sent to the SCC. All records sent to the SCC shall have the SCC identifier for internal record linkage.

2) Data Encryption - Data transmitted to the SCC shall be sent over the Internet, hence precautions shall be taken. Standard ASCII files (without variable identifiers) are encrypted using PKZIP and a password supplied to the site by the SCC. The encrypted data files are temporarily stored in the ftp area of mammstat.ghc.org. Within 24 hours the files are moved inside the GHC firewall to another computer. After the move the files are unencrypted.

3) Data Storage - The ftp area used by the SCC allows only the sites and NCI to logon. Once the files are moved to the computer inside the GHC firewall, only SCC staff shall have access to the data. The data are stored in Sybase with each file protected by a password. The data are resident only on a single computer and are not available on a network. To perform analyses, an analytic database is created that is then put on the network for use by the statistical analysts. Only analytic datasets shall be supplied to other users after approval by the publication committee.

APPENDIX A

Sample Confidentiality Agreement

ACKNOWLEDGMENT:
I have read and agree to abide by the standards set forth in the CONFIDENTIAL POLICIES AND PROCEDURES FOR DATA MANAGEMENT, National Cancer Institute Breast Cancer Surveillance Consortium, _____, dated 10/10/96.

I am employed by: _____
(Name of Employer)

_____
(Address of Employer)

___ I am a consultant/contractor on:_____
(Name of Project)

___ I am a review committee member on: _____
(Name of Project)

___ I am an investigator requesting data for research.

___ I represent public health efforts and am requesting data.

___ I work at a mammography/pathology facility and request data for quality assurance purposes.

I understand that any confidentiality violations may make me liable for civil and/or criminal penalties.

DATE: _____

NAME:

_____
(Please Print)

_____
(Signature)

ADDRESS: _____
(Street) (City) (State/Zip)

APPENDIX B

Sample Confidential Data Request Form

Complete this form and return with any required documentation to:

Name: _____

Address: _____
_____
_____

Name of Applicant:_____

Institution: _____

Address: _____
_____
_____

Telephone: _____ FAX: _____ Date: _____

Title of Project: _____

Exact Data Requested:

_____
_____
_____

Exact purpose for which these data are being requested and limits of data use:
Requests shall clearly state the limits of data use. Data may only be used for the exact purpose for which they are requested. Data may only be released for the purpose specified in the request.

_____
_____
_____

Dates data use requested to begin __/__/__ ; to end __/__/__ .
When data analyses are complete, data will either be destroyed or, if needed for later reference, maintained in locked storage in the custody of an applicant for a specified period until they are no longer needed.
Applicants will specify the exact time period in their request during which they will require access to data.

PLEASE CONTINUE ON TO NEXT PAGE

Names and positions of persons responsible for maintaining data confidentiality *(Data shall be kept confidential in the custody of the fewest individuals possible; these individuals will sign a written assurance of confidentiality).*

Names Positions

For data involving individual identifiers, requests shall be approved by the Institutional Review Board (IRB) prior to submission of the request to the registry.

This request has received IRB approval dated: _ _/_ _/_ _
(or)
The request does not require IRB approval. _____ Initial here

For requests requiring the use of personal identifiers, indicate precautions for providing the necessary confidentiality in accordance with IRB standards, which include reporting practitioner and/or patient data in sufficient aggregate to minimize the risk of identifying individuals or individual practice groups.

Applicant agrees to make a copy of any proposed publication or other form of public disclosure available to the registry 30 days prior to any public disclosure of data released from the Registry.

_____ _____
Signature Date

Applicant shall cover the cost of retrieving data for this request to provide for use of the data without expense to the registry. Cost shall be determined by the Registry Director.

_____ _____
Signature Date

NOTE: FAILURE TO ABIDE BY TERMS OF THE AGREED USE OF DATA MAKES THE APPLICANT LIABLE FOR LITIGATION.

APPENDIX C

Sample Advisory Committee Policies

New Hampshire Mammography Network - Guidelines for Advisory Committee

Selection of the N.H. Regional Breast Cancer Screening Network Advisory Committee members will be based on the following two criteria: 1) being a radiologist, mammography technologist, pathologist or researcher interested in and committed to the development of a mammography-pathology-tumor registry network that will enhance the quality of breast care in the state of New Hampshire and contribute to the study of breast cancer and breast cancer screening and, 2) having adequate geographic representation of mammographic centers state-wide.

Participation on this Committee will involve quarterly meetings. Attendance by conference call will be possible. The purpose of the Committee is to assist in the coordination and direction of efforts geared toward the implementation of the Department of Defense funded (DAMD17-94-J-4109) New Hampshire Regional Breast Cancer Screening Network. The primary responsibility of the Committee will be to determine policies and procedures that guide the conduct of this research. Membership terms will be reviewed annually.

The following are principles to follow and issues to consider regarding the collaborative efforts among members of the New Hampshire Regional Breast Cancer Screening Network Advisory Committee.

1) The Committee will keep in mind that the primary goals of this collaborative effort are to deepen our understanding of the practice of breast cancer screening and diagnosis in New Hampshire and elsewhere in the U.S., to further our understanding of breast cancer, and to produce high quality scientific work.

2) As its main functions, this Committee will help to develop the instruments needed for accurate data collection, and oversee the scientific activities and related analyses generated by the project. Members will be representatives of: New Hampshire radiologists and mammography technologists, the research team (including E. Robert Greenberg, MD, Patricia Carney, PhD, Steven Poplack, MD, Marguerite Stevens, PhD, Anna Tosteson, PhD), and a liaison from the state Health Department.

3) The Committee will meet quarterly for the first year of the project and semiannually thereafter for the remaining three project years.

4) Data Sharing:

a) As part of this project, data will be linked between the mammography and state tumor registries, both based in Hanover, New Hampshire and the New Hampshire State Department of Health and Vital Statistics, based in Concord, New Hampshire.

b) This project is part of the Breast Cancer Screening Surveillance Consortium, a consortium of eight federally-funded mammography programs, and it will contribute to both shared and pooled Consortium data. Pooled data is defined as analyses where site of origin or original population is disregarded. Shared data is defined as data from individual sites which may be analyzed and compared. Any decisions regarding data pooling and sharing will be made jointly by E. Robert Greenberg, M.D., Principal Investigator, and Patricia A. Carney, Director, and representative to the Breast Cancer Screening Surveillance Consortium Steering Committee with input from this Advisory Committee.

c) With the exception of contractual language (or grant language), data sharing will be done on a voluntary basis.

d) No identifying information will be part of any shared database.

5) Publications Policy:

a) A subcommittee of this Advisory Committee will sit as a publications advisory Committee.

b) A number of core analyses with the potential for turning into joint publications will be outlined by this Committee.

c) This Committee will draft a publications policy for the project and will establish a mechanism by which manuscripts can be shared among groups at the earliest appropriate time.

APPENDIX C

Manuscript in Progress on Medico-legal Issues in Confidentiality and Data Integrity

Medico-legal Issues and Protective Policies and Procedures for Data Integrity and Confidentiality in a Large Multi-center Research Program: The National Cancer Institute's Breast Cancer Surveillance Consortium

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by

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ABSTRACT

Managing confidentiality and integrity of data in today's realm of computerized communication systems is complex. There are good reasons for sharing and pooling data to address important public health issues yet protecting the confidentiality of those involved in the research is critical. The internet provides a convenient mechanism to transfer data from large collaborative trials to a singe data repository, however standards for managing data and data security are needed. We describe the process we undertook to understand the confidentiality issues in the eight states and three different settings that are part of a large multi-center consortium of mammography screening and breast cancer detection studies, all of which are contributing data to a centralized data repository. We also outline the policies and procedures we developed and implemented to protect professional (physicians, nurse practitioners, etc.) and lay (women undergoing mammography screening) participants. In developing these policies and procedures we learned that some variability by institution and by state in the types of protection exist. However, adequate security of data can be reasonably achieved if careful planning is undertaken.

INTRODUCTION

Information from patient's medical records with or without their knowledge has contributed to data amassed in large databases for years. Cancer registries have been operating in many states for decades, and other groups have proposed to design and develop national or regional registries for childhood immunizations (1), cardiovascular surgery (2), and mammography screening (3-7). Health Employer Data Information Set (HEDIS) performance measures derived from health maintenance organizations' databases provide another example of computerized databases. These databases (2) are commonly amassed for quality improvement or quality assurance purposes (3, 8) as well as for research. Though confidentiality and integrity of data has always been a concern in research and clinical settings, technological advances in data handling and the ability to share large data sets have made the process of protecting confidentiality more challenging. We must carefully balance that which must be obtained or monitored for the public's good with a respect for privacy and anonymity.

Because these databases often contain confidential patient information as well as aggregated data on physician performance, medico-legal issues are of utmost importance. Cancer registries and other databases used for research have relied on laws in the respective states to protect data used for research. Institutional Review Boards are designed to protect the confidentiality of and ensure ethical treatment of human subjects, but variability exists in federal regulations due to interpretive issues. Inter institutional and interstate use of data may also leave researchers vulnerable to having these legal protections challenged. Computerized databases have relied on several different types of Peer Review or Quality Assurance (QA) Statues to confer protection from discovery (9). However, the value of QA statutes in protecting the confidentiality of research databases is not clear. A key factor in the strength of legal protection may be how information is handled and by whom and whether a legal precedent has been set.

Missing from the confidentiality literature is an outline of both approaches to take to identify relevant medico-legal issues and policies and procedures that can reasonably be implemented on an institutional or multi-institutional basis to provide consistent confidential

handling of all data (paper and electronic), including data reports and data used for research or improvement purposes. We outline here recommended approaches to address medico-legal issues as well as the policies and procedures we developed and implemented as part of a large multi-center consortium studying breast cancer screening, including applications of state and federal laws, the essential steps for appropriate data collection, storage, utilization, sharing, and confidentiality and security guidelines for data transfers between the Consortium member sites to the Statistical Coordinating Center. Our intention is to provide a clear framework for protecting research participants and insuring integrity of data involved in confidential medical research. Compliance with these policies and procedures by all consortium member sites can ensure both the confidentiality and integrity of such data.

BACKGROUND OF THE NATIONAL CANCER INSTITUTE'S BREAST CANCER SURVEILLANCE CONSORTIUM

The nine National Cancer Institute Breast Cancer Surveillance Consortium sites are located in California, Colorado, Iowa, New Hampshire, New Mexico, North Carolina, Vermont, and Washington state (n=2). The three major purposes of the Consortium are to 1) enhance our understanding of the operation and conduct of breast cancer screening in the United States, in part to respond to a congressional mandate in the Mammography Quality Standards Act (MQSA); 2) foster collaborative research among participants of the Surveillance Consortium to further our understanding of breast cancer screening; and 3) provide a foundation for the conduct of research, including basic biological mechanistic research, aimed at improving our understanding of the natural history of breast cancer.

The Consortium is described in detail elsewhere (10). Each Consortium member site, has established a computerized registry with data from designated mammographic facilities within a specific geographic region. These registries establish linkages to the regional population-based National Cancer Institute's (NCI) Surveillance Epidemiology and End Results (SEER) registry or statewide cancer registry in order to assess various screening or diagnostic outcomes, such as

predictive value, sensitivity and specificity of mammography, practice patterns, and in some cases the costs associated with follow-up of abnormal mammographic results in the community.

Each Consortium member site collects, stores, utilizes, and transfers confidential data on mammography patients, physician's radiologic reports, and follow-up information, including pathology outcomes. These include clinical and epidemiologic data that are routinely collected on patients receiving mammography. These data may be used in collaboration with other investigators who may or may not be Consortium members. The National Cancer Institute has funded a Statistical Coordinating Center, to which each site sends data for pooled analysis.

Soon after the Consortium was formed, we conducted an assessment to determine how each member site protects the confidentiality of their research subjects by obtaining copies of institutional and state regulations and laws that protect the data from both disclosure and litigation. We also collected policies and procedures regarding each sites' management of paper or computer research data systems. This assessment revealed great variability in managing confidentiality issues. To apply a more standardized process, we developed and implemented a minimum set of standards for the protection of research participants and the data they contribute. In this manuscript, we outline that policy, including our definitions of confidentiality; the responsibilities of Consortium member sites; state and federal protection; data access; and paper and computer data security.

DEFINITIONS OF CONFIDENTIAL INFORMATION

Consortium member sites first decided upon a uniform set of definitions for confidential information that would protect both lay and professional participants of the research. Confidential information is information that contains identifying data that link it to a specific research participant. Such identifying information includes: patient, physician or facility name, address including zip code, telephone number, social security number, and/or occupation and employer.

Information generated by each member site is classified into three categories based on the repercussions, such as loss of statutory protection, that may occur from unauthorized disclosure.

These categories and their definitions are outlined in **Table 1**. All data and information that identify patient, physician or facility specific information are considered confidential. Information that characterizes the case load of a specific institution or health care professional is considered proprietary and confidential because the volume could identify the site or individual.

RESPONSIBILITIES OF EACH CONSORTIUM MEMBER SITE

Each Consortium member's intent is to balance its research endeavors with its commitment to protect confidential information obtained and generated in the course of that research. It is their policy to adhere to laws and regulations that govern the collection, compilation, use, transfer, and storage of confidential data; to protect this information from unauthorized access or use at all time; to assure that this information will only be transferred, utilized, and/or stored in sanctioned and approved ways; to assure that breaches of this policy are reported promptly and that appropriate corrective and/or disciplinary measures are taken; and to respond promptly to inquiries from concerned participants regarding their research and other activities.

Each consortium member site must protect the data from unauthorized access and release, using the same standards of confidentiality that customarily apply to the physician-patient relationship and the confidentiality of medical records. This obligation extends indefinitely, even after the patient is deceased or the physician ceases practicing within the area.

Federal and State Laws and Regulations

Collection, access, use, and disclosure of confidential data pertaining to study subjects entered at each Consortium member site is governed by federal and state statutes and regulations. Each Consortium member site must comply with these laws to the fullest extent possible to meet its obligations to funding sources and to meet its commitment to ethical principles upon which human subjects regulations are predicated. Laws vary by state depending on the type of protection that has been legislated for protection. The strongest possible legal protection exists where there are laws to protect confidentiality of data either from use in litigation or from disclosing identifying information.

In order to proceed with research that involves human subjects in the United States, approval by an Institutional Review Board (IRB) as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46 subpart A, June 18, 1991) is required. The review and approval process for IRB's must include a determination that each proposal meets specified criteria contained in these regulations, including: standards for review of risk, selection of subjects, informed consent, appropriate safety monitoring, privacy, and confidentiality (45 CFR 46.111 (a)). All the Consortium members received approval to conduct their respective research as designed. As part of the IRB review, issues of potential risk to participants are analyzed to determine whether the risks are minimal and acceptable.

Confidential protection is one of the risks reviewed. Risks associated with breaches in confidentiality are weighed with the overall benefit of the research for the individual and society and a determination is made by applying federal guidelines as to whether the research can proceed. The regulations for human subjects set out four criteria, all of which must be met in order for an IRB to allow an alteration to some or all of the elements of informed consent or to grant a waiver of informed consent (45 CRF46.116(d)). Consortium sites collect existing medical information from radiology records, cancer registries and pathology laboratories and prospective data from forms that women and radiologists complete at the time of the mammogram. Seven Consortium sites requested a waiver of informed consent, which were granted. Two of the sites that were granted the waiver of informed consent provide passive consent information on the data collection form that women complete. In both instances if a woman chooses not to have her data used for research then her decision is respected. Two sites were required to ask for active consent and currently get a copy of the signed consent form mailed to them for each participant. Four of the nine (44%) IRB applications cite state laws that offer protection to the data for confidentiality.

In 1996, the Breast Cancer Surveillance Consortium Members applied for and received Federal Certificates of Confidentiality in accordance with the provisions of section 301(d) of the Public Health Service Act (42 U.S.C. 241 (d)). This certificate is issued to protect the privacy of research subjects by withholding their identities from all persons not connected with the research.

Under Section 301(d), no federal, state or local civil, criminal, administrative, legislative, or other proceedings can be used to compel disclosure of identifying characteristics of research subjects (14). This level of protection is the strongest and most comprehensive currently offered by applicable `law, and legal precedent exists to support the strength of this coverage (**Cite Newman case**). The protection this certificate affords can extend to women and professional participants (radiologists, mammography technologists, pathologists, surgeons and primary care providers) who contribute data to each Consortium member site.

The decision to obtain the Certificate was made when a medico-legal analysis of federal and state regulations was conducted by the Consortium and the strengths and weaknesses available in other forms of protection was discovered. The medico-legal analysis revealed that State laws protecting the confidentiality of records used in medical research can be divided into five general categories: 1) laws specifically applicable to confidentiality of records used in medical research; 2) laws specifically applicable to cancer or mammography registries; 3) confidentiality requirements under quality assurance or peer review statutes; 4) laws creating a physician-patient privilege; 5) and laws generally applicable to the confidentiality of medical records. Protection afforded under all five types of legislation varies from state to state within the Consortium, although the first category consistently provides the most comprehensive protection for information collected in connection with medical research.

Caveats that exist under Category 1 include issues that vary by state, such as that statutes may or may not extend their coverage to include professional participants and they may or may not address disclosure of either information of identity of participants. Those that exist under Category 2 also vary by state and may or may not extend coverage to patients who do not have certain forms of cancer.

Under Category 3, QA statutes and the strength of the protection they afford also vary widely from state to state. The only safe generalization is that they will be narrowly construed in malpractice cases because they run counter to the general rule that a court will admit all relevant evidence with probative value in order to aid in ascertaining the truth and resolving disputes

between litigants. Thus a court may find that a particular QA statute will not apply to protect the confidentiality of data if:

1) the data are not within the class of information protected by the statute (typically, "records" generated by a quality assurance, peer review, or medical staff "committee").

2) the statutorily required formalities have not been followed (e.g. in some states, the committee must be a "regularly constituted review committee" of a hospital medical staff).

3) the protected data are not systematically used to evaluate and improve the quality of patient care (this occurs in some Consortium sites but not others).

4) a statutory exemption applies (e.g. for suits brought to challenge denial of medical staff privileges in certain states but not others; or

5) the Consortium member site cannot demonstrate that internal controls are in place to protect the confidentiality of the protected data.

Under Category 4, these laws generally indicate that patients have the authority to prevent physicians from revealing privileged information without the patient's consent. The privilege generally applies to confidential communications between a patient and his/her physician, though the privilege must yield if the information is deemed essential to the case before it. Though these privileges do not appear to apply directly to medical records used in medical research, if a published study prompted questions about a particular providers treatment of patients, the provider could refuse to disclose information. Though these laws provide no protection to the provider if a patient agrees to a disclosure.

For Category 5, many states have a Patient's Bill of Rights. These laws usually state that patients have the right to expect that communications and records pertaining to their care will be treated as confidential and not disclosed without their authorization. While these laws do not provide a distinct additional category of protection for information collected by medical researchers, they do support the concept that medical information is confidential.

POLICIES AND PROCEDURES FOR HANDLING DATA

In addition to assuring that the data are protected from legal discovery, the Consortium must be vigilant in protecting data from any use that might bring harm to the participants. To accomplish this each site has established systems to physically protect the data and rules to prevent the misuse of data. A policy and procedures manual was developed by Consortium members to bring a basic level of uniformity to data handling and access. All Consortium members agreed that confidential data would not be transmitted from the site by any means (mail, telephone, electronic, or facsimile) without explicit authority from the Principal Investigator or a staff member to whom such authority has been delegated. The specifics of the data (i.e. variables, date range) and to whom it would be transmitted must be clearly communicated in writing to staff. Besides each sites' staff handling data and contributing data, there are several other categories of people who may also need or want access to these data.

- **Monitoring Access to the Data**

Staff members at all sites require access to the data to conduct their work. Each staff member is required to read the Confidentiality Policy and Procedures Manual and sign a pledge to uphold this policy. The pledge remains in effect after cessation of employment. Consortium sites maintain a historical file of staff members who have signed pledges. The orientation and training of each new staff member includes instructions concerning the confidentiality of data.

The Consortium member sites who contract with computer programmers, biostatisticians or contractors and consultants who have access to restricted information must have these individuals read the Confidentiality Policy and Procedures Manual and sign a confidentiality agreement with assurances that they will safeguard such information from unauthorized access or further disclosure.

Investigators or public health officials may request access to confidential or aggregate Consortium member data. All requests must be made in writing and approved by the Principal Investigator or an advisory body, such as a steering committee made up of community

radiologists/pathologists and members of the site's research team. If an advisory committee is used, a description of how the committee members are chosen or elected, their length of term and the procedures used to approve a request must be outlined, including criteria (majority, unanimous, quorum), time from request to approval, and notification. All procedures must be followed and documented. All persons given access to data must read the Confidentiality Policy and Procedures Manual and sign an agreement to adhere to the same confidentiality standards practiced by sites' staff members. A formal data request form will be used for every request.

All requests for data to be used in research must be approved by respective IRBs prior to submission of the request to the Consortium member site. Requests requiring the use of personal identifiers should indicate precautions for providing the necessary confidentiality in accordance with IRB standards, which includes reporting patient, practitioner and facility data in sufficient aggregate to minimize the risk of identifying individuals or individual practices. All requests must clearly state the limits of data use. Data may only be used for the exact purpose for which they are requested. Data must be kept confidential in the custody of the fewest individuals possible.

Data may only be released to the public for the purpose specified in the request. When data analyses are complete, data must either be destroyed or, if needed for later reference, maintained in locked storage in the custody of an applicant for a specified period until they are no longer needed. Applicants must specify the exact time period in their request during which they will require access to data.

All applicants must agree to make a copy of any proposed publication or other form of public disclosure available to Consortium member sites 30 days prior to any public disclosure of data released from the Consortium member site. This will ensure adequate time to review, comment or decide to reanalyze and provide a response or alternate explanation, if necessary.

Confidential data are never available, to the extent allowed by law, for uses such as businesses or industries that desire to market a product or service to patients; health care institutions, their employees or providers that may want to advertise or identify new patients for

recruitment; or insurance companies that are attempting to determine the status of an individual for any reason.

A subset of the data collected at each Consortium member site is transferred to the Statistical Coordinating Center of the NCI's Breast Cancer Surveillance Consortium, located in Seattle, Washington. The data so transferred do not include personal identifiers. As a member of the Breast Cancer Surveillance Consortium, the SCC has the same standards of confidentiality as all the member Registries.

DATA SECURITY - PAPER SYSTEMS

The following components are required to assure data security in all areas of Consortium member site operation. Suitable locks are installed to control access to the site and custodial staff are notified of the importance of maintaining a secure environment. A roster of persons authorized to enter the area is maintained by the Consortium site administrative personnel. Staff are responsible for the confidentiality of all data encountered during data collection.

A site-developed mail tracking system must be used to protect confidential data. The physical security of confidential data stored on paper documents, computer printouts, microfiche and other media present from each Consortium member site is ensured. Confidential documents to be destroyed are kept in a secure environment until they are shredded and disposed of properly.

Many of the consortium member sites produce QA reports for practitioners and facilities at designated intervals. Report handling constituted the area of greatest concern in developing this policy. Despite each site's attempts to obtain institutional, state and federal protection of the databases and their contents, misuse of reports could negate all the legal protection originally obtained for database protection. An example of misuse would be a site that used a report for marketing purposes. Inappropriate release of data could damage an individual whose diagnosis of cancer is made public; facilities and physicians could be severely compromised if accuracy or practice pattern data are disclosed. While legal protection of the data from discovery is necessary

to assure that no harm comes to people contributing to the database, these same individuals have an equal responsibility to maintain the confidentiality of their reports.

For Consortium member sites that provide QA data to contributing facilities/physicians, all physicians can receive reports on their own patients as per agreement with the site. These reports may contain identifying information on them. Any report that contains patient level information must be treated as confidentially as any medical record. Encrypted codes may be generated when appropriate each time a report is created to protect the identity of a receiving facility or radiologist. These codes will never be able to link participants to actual study identifiers.

Some sites are using a two step process for generating reports, where two individuals are responsible for report handling within a site, one is kept blind to the encrypted code, but has access to the database for report production and one is kept blind to the data source, but applies the encrypted code for processing and ultimate mailing. Some sites have also elected to report practitioner and/or patient data only in sufficient aggregate to minimize the risk of identifying individuals or individual practice groups. Thus, any cells that have a small number of cases (which may identify an individual or a facility) are suppressed in those reports. The purpose of the reports are clearly printed on them or accompanying information. All requests for QA data from other persons within the mammography facility must have written approval from the physician or his/her designate physician in charge of quality assurance at said facility.

DATA SECURITY - COMPUTER SYSTEMS

Computers are located in a locked facility with no access to public traffic. Computer security safeguards include the following. Patient identifiers and demographic information are stored in files that contain no other information. Other data are stored in separate computer files in the database. They are linked by a scrambled code that can only be accessed by authorized personnel.

Password protection is required to enter each Consortium member sites' computers, applications and databases. All users accessing the database have a unique identification code and

password. Passwords are changed on a regular basis. A user's identification and password are invalidated when the individual no longer requires access to the database. Precautions are taken for both physical and electronic security of confidential data sent on magnetic or electronic media. Secure telephone data transmission using an unlisted telephone number, password access to the bulletin board systems, and restricted use of facsimile protect confidential data transmissions.

Backup disks or tapes have no identification on them other than numbers or codes and a generic office address label. Caution is taken to protect disks when off site by knowing where they are at all times and never leaving them in an unsecured location.

All word processing files that contain codes, passwords, data dictionaries or any descriptions of how to interpret the data are stored in password protected files or removed from computers, copied on to disks/tapes and stored in locked cabinets. An in-house printer is used for the printing of confidential data, and these data are never be left unattended in the printer. The use of personal and notebook computers for the ascertainment and management of confidential data is controlled by the same electronic and physical measures as described previously to protect the security of the data. Training and demonstration of computer systems are performed with separate fictitious and/or anonymous data sets. All disks/tapes containing Consortium site data are erased when not actively used for backup or transmission of data.

All study identifiers at the site are recoded to a new SCC study identifier. To perform the recode, the SCC distributed a program based on a published algorithm (12). The new SCC identifier cannot be reverse engineered to yield the original identifier. The algorithm is used to recode subject identifiers, radiologist identifiers, and radiology site identifiers. Only encrypted identifiers are ever sent to the SCC, all of which have the SCC identifier for internal record linkage.

Data transmitted to the SCC are sent over the Internet, hence precautions are taken. Standard ASCII files (without variable identifiers) are encrypted using PKZIP™ and a password supplied to the site by the SCC. The encrypted data files are temporarily stored in the file transfer protocol area of a SCC computer designated to receive data from the internet. Within 24 hours the

files are moved inside the SCC firewall to another computer. After the move the files are unencrypted.

The file transfer process area used by the SCC allows only the sites and National Cancer Institute to log on. Once the files are moved to the computer inside the SCC firewall, only SCC staff have access to the data. The data are stored in a master relational database with each file protected by a password. The data are available only on a private internal network accessed only by SCC statistical personnel. This network is not connected to the Internet. Only analytic data sets are be supplied to other users after approval by the publication committee.

DISCUSSION

A critical issue is the balance between the conduct of research for the good of the public's health and the protection of an individual's right to privacy. Large multi-site database studies, such as those being conducted by the NCI Breast Cancer Surveillance Consortium, can provide important data for shared or pooled analyses critical to addressing important public health issues. The major risk to both patient and provider participants is disclosure of potentially sensitive information and loss of confidentiality of identifying information. We worked collaboratively as a Consortium and legal consultation to identify, analyze and outline how best the nine partnership sites could protect the confidentiality and integrity of data and databases as well as those participating in our research projects. Our efforts identified several issues that deserve further discussion.

First, our review of each Consortium member sites' regulations, statues and laws for protection of research subjects yielded unexpected variability. We learned that though federal regulations guide IRBs for the protection of human subjects, the interpretation of these regulations varied by institution. Research may be considered any systematic investigation in which a researcher obtains data through intervention or interaction with an individual or identifiable private information. We found that requirements and definitions of active and passive informed consent differed by institution and that gaining access to medical records with or without active informed

consent is becoming an increasingly controversial issue for IRBs. We learned, too, that the term "participant consent" can have very different definitions. "Informed" consent pertains to an agreement to participate in research testing an experimental treatment or procedure. An additional definition of participant consent pertains to the disclosure of certain identifying information that the study participant (subject) has agreed to share within the confines of a research study, such as access to their medical record. It is critical that researchers develop and implement policies that will insure the physical (including computerized) protection of research data, such as those we have outlined here. IRBs review studies annually and for one site this annual review has resulted in being required to provide more information to patients than had initially been required.

The IRB's purpose is to ensure adequate protection of human subjects who participate in research. Federal regulations for IRB's provide the guiding posts for deciding when it is appropriate to alter or waive elements of informed consent. The following four conditions must be met before a waiver or alteration can be approved: 1) the research involves no more than minimal risk to the subject; 2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; 3) the research could not practically be carried out without the waiver or alteration; and 4) whenever appropriate, the subjects will be provided with additional pertinent information after participation (45 CFR 46.116(d). Based on these criteria, all sites but one that applied for the waiver were granted it. IRB Guidelines can be interpreted differently at each institution. What some sites would consider minimal risk or practice may vary. It would not be feasible for most of these sites to carry out their research if informed consent was required. For example, one site starts with the SEER registry data and identifies breast cancer patients, then finds whether a mammogram was done prior to the diagnosis. In this instance contacting the patient for consent would be intrusive and the cost of seeking the consent would make the research unfeasible while the risk to the woman is truly minimal. Breach in confidentiality is the major risk to patients in these studies and the consortium sites have very carefully constructed systems to maximize confidentiality of the data.

Many of the Consortium sites have research projects in which active consent is obtained. Although most sites have a waiver or alteration of informed consent, if new research were to occur later that would require identifying information to contact participants this would once again go before the IRB for approval. In this instance, the researcher would most likely be required to obtain permission to contact patients and get informed consent either through or by their physician provider.

IRB's are interested in knowing who the research subjects are, how they will be recruited and what the benefits and risks are for each type of subject. When applying for IRB approval it is important to identify all the appropriate research subjects. When most of the consortium sites applied for IRB approval, they only listed the women getting mammograms as research participants. Several IRB's asked the researchers if the radiologists or pathologists were also research participants. The professionals who contribute data to the projects are indeed research subjects since we are studying mammography quality indicators. Those sites who initially did not have professionals listed as research subjects have gone back to their IRB's requesting that they be so designated.

Though state and federal laws can both prevent the release of individual level information and protect data from use in litigation (12-14), this protection can be threatened by misuse of data or report handling (15, 16). Institutions and individual practitioners have relied on the QA or peer review statutes in their respective states to confer protection from discovery for a variety of review and clinical improvement activities. In many instances the protection, in fact, never existed, due to the manner in which information was gathered, processed and the results distributed. In order to maintain protection, the information must be identified and handled in a manner defined by the wording of the statute providing protection in that state.

Most states have laws which provide varying degrees of confidentiality protection to different kinds of medical records. However, the differences in the applicability of these laws can be significant. This issue is becoming increasingly controversial (17, 18), as the public has become more aware of occurrences of misuse of the medical record. These have included sales of

medical records and release of medical information to federal program auditors and mortgage holders (17). At least two recent legislative proposals have been considered by US Congress that deal directly with attempts to ensure privacy of identifiable health information, such as the medical record (17). In one, the collection and use of information would include the informed consent of the individual, specific rules would be enacted regarding disclosure, physical security would be mandated, and an independent oversight body would be appointed by US Congress.

It is now important for researchers who intend to collect data for research purposes to rely on current laws and monitor future legislation, to be familiar with the specific requirements within their own jurisdictions, to research legal precedents that can give an indication of the strength of the protection, and to institute measures to insure that databases, data reports, other research information can be protected from disclosure and the confidentiality of identifying information can legally be protected.

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Table 1 Categories and Definitions of Confidential Information

Category of Information	Definition
Public Information	Information or data collected, compiled, utilized, or generated which is intended for public distribution and use or which may be obtained under freedom of information legislation. Generally, this includes aggregated data in published form, such as articles in medical journals about mammography patterns of care, accuracy, and other related topics. This does not include confidential information.
Internal Information	Information or data collected, compiled, utilized, or generated by the organization which may be shared with employees and authorized consultants and contractors only. Authorization for external distribution or access must be obtained from the Principal Investigator. Examples of internal information include mailing lists and technical proposals or software manuals.
Restricted Information	Confidential information collected, complied, utilized, and/or stored by the organization which contains identifying links with specific individuals or medical practices such as name, address, or social security number. Confidential mammography registry data and reports fall within this category, as do any personal identifiers collected as part of Registry. Proprietary data or information produced by employees, consultants and/or contractors also falls within this category.

Table 2 Types of Protection Offered by Federal or State Governments and Individual Institutions

Federal Types of Protection

- Public Health Service Certificate of Confidentiality
- Federal Laws on Instutional Review Boards

State Types of Protection

- Laws Protecting the Confidentiality of Records used in Medical Research
- Laws protecting Cancer or Mammography Registries
- Quality Assurance Statutes
- Laws Regulating Physician-Patient Privilege
- Laws on Patient's Bill of Rights

Institutional Types of Protection

- Gaining Appropriate IRB approval
- Other Core Components for Data Protection

1. Limiting Data Access with Key or Password Protection
2. Outlining the Specifics of All Data Handling Using a Standardized Protocol
3. Shredding Unneeded Paper Data
4. Formalizing all Data Requests and Establish a Review Process for Release of Research Data
5. Developing a Firewall for all Computer Systems
6. Maintaining off-site Backups of Computerized Databases
7. Using a Specially Designed Encryption Program to Convert Data before Sending it over the Internet

APPENDIX D

Study Paper Data Collection Instruments

A 0 0 9 1 5 4 5

MAMMOGRAPHY FACILITY MUST COMPLETE

Patient's Medical Record #: _____

Patient's Date of Birth: ____ - ____ - ____
MM DD YY

NH Mammography Network General Information

Patient's Name: _____
Last First Middle

Address: _____

_____

_____

Zip code: _____

Today's Date: ___ - ___ - ___
month day year

PLEASE CLEARLY PRINT ALL INFORMATION

Please read the information below before you fill out the attached survey.

Information about the New Hampshire Mammography Network Project

Your mammography center is working with the Norris Cotton Cancer Center and Dartmouth Medical School to develop a registry (a computer database) of mammograms that will help us understand breast problems, including breast cancer. The registry is called the New Hampshire Mammography Network. It collects information on all mammograms performed in New Hampshire, including the procedure you are having today. It is used to help your facility comply with Federal regulations that all mammography facilities must meet.

We are asking you to help us expand the usefulness of this registry by giving us additional information on the attached survey. The survey is for research purposes only. It is not part of your routine procedure for mammography. **Your participation is strictly voluntary. Whether you participate or not, your decision will have no effect on your medical care.**

The information you give us on the attached survey will be entered into our New Hampshire Mammography Network, along with your mammography results. However, if you are a resident of Vermont, your information will be transferred to a similar registry in Vermont. Neither our registry nor the Vermont registry will release any information that allows you to be identified. Although data collected may be shared with other investigators, your name and other identifying information will not be revealed.

If, after your mammogram, you have additional diagnostic studies or treatment related to breast problems, we may need to review your medical records to help us fully understand your mammography results. Rarely, we also may wish to contact a patient or her doctor directly to ask for more information. This may occur once or twice for every 200 mammograms we receive.

Please Note: If there are any questions on the survey that you do not wish to answer, simply leave them blank. If you do not wish to participate in this research study, please hand all the forms back to the receptionist or mammography technologist.

If you have any questions regarding the NH Mammography Network Project, please call the Norris Cotton Cancer Center at 603-650-4135. Ask to speak with Karen Burgess or Patricia Carney.

Permission: We ask your permission to use your data in our project, and, if needed, to review your record or to contact you or your doctor for additional information. Please sign here to indicate that you are willing to participate fully in these activities.

Signature:_____

Thank you for your cooperation!

final 4/96

49344

NH Mammography Network
General Information

A 0 0 9 1 5 4 5

Instructions:

Please complete this questionnaire using a No.2 pencil or blue or black pen.
All letters and numbers must be written in capital block style **without touching the sides.**

0	1	2	3	4	A	B	C	D	E

Please shade circles like this: ●

1. MAMMOGRAM HISTORY

Are you having a mammogram today because: (Choose one)

- ○ **Both you and your health care provider** are concerned about a breast change (lump, pain, etc)?
- ○ **You** are concerned about a breast change?
- ○ **Your health care provider** is concerned about a breast change?
- ○ **Routine Screening Exam** - no breast changes but I or my health care provider wanted a routine mammogram?

When was your last mammogram? (Choose one)

- ○ Within the last 12 months
- ○ 1 to 2 years ago
- ○ 3 to 4 years ago
- ○ 5 or more years ago
- ○ Never had a mammogram before

When did a health care provider last examine your breasts? (Choose one)

- ○ Within the last 12 months
- ○ 1 to 2 years ago
- ○ 3 to 4 years ago
- ○ 5 or more years ago
- ○ Never

2. PERSONAL HISTORY

What is your date of birth?

		/			/				
M	M		D	D		Y	Y	Y	Y

What is your social security number?

			-		-				

(To Avoid Duplication of Records)

What is your racial or ethnic background? (optional) (Choose one)

- ○ White/Caucasian
- ○ Black/African-American
- ○ Native American (American Indian)
- ○ Hispanic/Latina
- ○ Asian/Pacific Islander
- ○ Other (please specify) _____

What is your maiden name (last name only)?

Where were you born?

○ USA ○ Other _____

If born in USA, in which state were you born?

State (e.g. NH, VT, MA, ME, etc.)

What is your current marital status? (Choose one)

- ○ Single ○ Divorced
- ○ Married ○ Widowed
- ○ Separated

Please turn over to continue...

49344

A 0 0 9 1 5 4 5

2. PERSONAL HISTORY (Contd.)

What is the highest level of education you have completed? (Choose one)

- O 8th grade or less
- O Some high school
- O High school graduate
- O Associate's degree or some college/tech school
- O College graduate (4 yrs)
- O Postgraduate

What is your health insurance coverage?
(Please shade all that apply)

- O None
- O Private Insurance (Blue Cross, AETNA etc)
- O Medicare
- O Medicaid
- O HMO or PPO (Preferred Provider Organization)
- O CHAMPUS, CHAMPVA or similar
- O Other: _____

What is your current height?
(to the nearest inch)

Feet Inches

e.g. 5 ft 6½ ins. = 5 0 7

What is your current weight?

Pounds

e.g. 98 lbs. = 0 9 8

What did you usually weigh (when not pregnant) when you were between 18 and 20 years old?

Pounds

3. HEALTH HISTORY

How old were you when you had your first menstrual period? (Choose one)

- O Under 11
- O 11
- O 12
- O 13
- O 14
- O 15 or older

Have your Periods stopped permanently?

O No O Yes

If Yes, did your Periods stop due to:
(Choose one)

- O Natural Menopause
- O Surgery (Hysterectomy)
- O Radiation or Chemotherapy
- O Other: _____

Have you ever had an ovary removed?
(Choose one)

- O No Ovary Removed
- O Yes, One Ovary Removed
- O Yes, Both Ovaries
- O Yes, but Don't Know if One or Both
- O Don't know

How old were you at the time of your first full term pregnancy? (by full term we mean a pregnancy lasting 6 months or more)
(skip if not applicable)

Age

How many times have you been pregnant, if ever? (can be zero)

Number of Full Term Pregnancies + Number of Early Pregnancy Losses = Total Pregnancies

Thank You!

48440

Patient Intake (Tech.) Form

B 0 0 9 5 5 1 8

DATA LINKS

Name: _____ (Last) _____ (First) _____ (Middle Initial)

Date of Exam: ____ - ____ - ____ (mm dd yy)

Social Security #: _____ - _____ - _____

Zip Code: _____

Date of Birth: ____ - ____ - ____ (mm dd yy)

Tech Initials: _____

Referring Physician's Name: _____

Referring Physician's Town: _____

Medical Record #: _____

Did the Patient read & sign the NHMN Survey Consent Form?

O No O Yes

Has the Patient had a previous mammogram?

O No O Yes

Date of Last Mammogram: ☐☐ / ☐☐ / ☐☐ (m m / d d / y y)

Location/State: _____

Does the Patient have any breast concerns?

O No O Yes

If Yes, who **first** became concerned? (choose ONE)

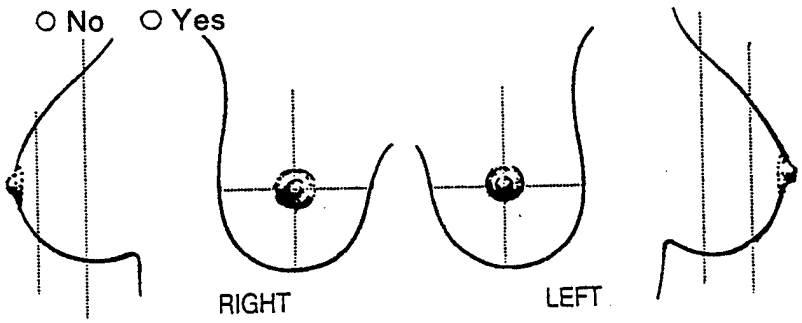
O Self O Partner O Physician/Nurse

How long has there been concern? (e.g enter 01 for 1 month or less) ☐☐ Months

Type of concern:	L	R	B	
Lump	O	O	O	
Nipple Discharge	O	O	O	
Skin Changes	O	O	O	
Other (please specify)	O	O	O	_____

Has the Patient had any past breast procedures?

O No O Yes



Type of procedure:	L	R	B	Date(s) Completed
Breast Reduction	O	O	O	_____
Breast Implants	O	O	O	_____
Needle Biopsy	O	O	O	_____
Surgical Biopsy	O	O	O	_____
Lumpectomy	O	O	O	_____
Mastectomy	O	O	O	_____
Breast Reconstruction	O	O	O	_____
Radiation Therapy	O	O	O	_____

Comments: _____

Has the Patient ever had breast cancer?

O No O Yes If yes, age at diagnosis? ☐☐ Age

Which breast? L O R O B O

How many **sisters/daughters** with breast cancer? ☐

Is there a family history of breast cancer?

O No O Yes O Unknown (e.g. adopted)

If yes, please specify: O Mother O Sister(s) O Other O Daughter(s) ☐

Have the Patient's periods stopped permanently?

O No O Yes O Not Sure

If yes or not sure, is she currently taking hormone replacement therapy? O No O Yes

If yes, how long? _____

4/18/96

48440

New Hampshire Mammography Network
Radiologist Interpretation Form

B0095518

Please be sure that the patient's name and data links are completed on the other side!

Please shade circles like this: ●

1. TYPE OF EXAM: (Choose ONE per breast)

B ○ L ○ R ○ **Asymptomatic** (Screening Mammogram)

	L	R	B
Screening & Additional Views (Single Aggregate Report) . .	○	○	○
Diagnostic Mammogram (for Clinical Indication)	○	○	○
Follow-Up at Short Interval (to Evaluate Stability)	○	○	○
Additional Views to Supplement Recent Mammogram (Reported Separately from Screen)	○	○	○

2. Were **COMPARISON MAMMOGRAMS** used for interpretation? ○ No ○ Yes

3. Was **BREAST ULTRASOUND** used to complete the assessment? ○ No ○ Yes

4. BREAST COMPOSITION: (Choose ONE and code by densest breast)

○ Fat ○ Scattered ○ Heterogenously Dense ○ Extremely Dense

5. ASSESSMENT STATUS: (Choose ONE per breast)

B ○ L ○ R ○ **Negative (ACR 1)**

	L	R	B
(ACR 0) Assessment Incomplete	○	○	○
(ACR 2) Benign Finding-Negative	○	○	○
(ACR 3) Probably Benign Finding	○	○	○
(ACR 4) Suspicious Abnormality	○	○	○
(ACR 5) Highly Suggestive of Malignancy	○	○	○

6. RECOMMENDATION: (Choose all that apply)

B ○ L ○ R ○ **Routine Screening Mammogram**

	L	R	B
Follow-up Mammogram at Short Interval . . .	○	○	○
Additional Views to Supplement Current Exam	○	○	○
Breast Ultrasound	○	○	○
Clinical Breast Exam	○	○	○
Surgical Consult	○	○	○
Biopsy (including FNA)	○	○	○

in ☐☐ months

Additional Comments (optional): _____

Rad. Initials ☐☐☐

4/18/96

APPENDIX E

Insight Contract and Data Collection Screens

Insight's Mammography Patient Manager Systems Proposal for The New Hampshire Mammography Network

Presented To:

Deirdre O'Mahony
New Hampshire Mammography Network
1 Medical Center Dr.
Lebanon, NH 03756
(603) 650-4140

From:

Eran Peery
Director

Proposal Date:

January 30, 1997, Revision 3
Valid for 30 days

Introduction

This proposal highlights the products and services that Insight will provide the New Hampshire Mammography Network (NHMN) and the mammography centers participating in the NHMN research project. Presented in good faith to Deirdre O'Mahony and the research team of NHMN, this document is intended to build the foundation for a long lasting, mutually beneficial relationship between Insight, the NHMN, and breast centers throughout New Hampshire.

The proposal covers the following topics:

1. Customization of MPM based on NHMN requirements
2. Pricing, terms, and acceptance
3. General guidelines and time tables
4. Implementation of MPM into client sites
5. Continued and on going support of both NHMN and client sites

By implementing a customized version of Insight's Mammography Patient Manager (MPM) for Windows into New Hampshire mammography facilities participating in the NHMN project, we are providing facilities with the tools they need for good patient management and MQSA compliance while giving the NHMN an automated data collection system.

Our goals are to:

1. Work closely with the NHMN to customize MPM for Windows to help achieve project goals.
2. Implement necessary modifications while still allowing for continued system updates.
3. Integrate MPM into participating sites' daily operations and work flow in a quick, easy manner.
4. Develop the necessary materials, setup and training protocols to ensure client success.
5. Provide client sites with a much needed tool for patient tracking, follow up, quality assurance, ...
6. Automate the data collection process for NHMN, saving time and ensuring integrity.
7. Provide NHMN and client sites with dedicated, knowledgeable support services.
8. Promote NHMN activities and project goals wherever appropriate.

NHMN Customization of The Mammography Patient Manager

MPM is an excellent patient management tool well suited for today's mammography centers. In customizing MPM for NHMN, our goal is to allow facilities to easily and fully participate in NHMN's research project while fulfilling their own management needs. The following is an overview of the areas of the proposed customization and applies to the upcoming release of MPM for Windows:

1. Adapt MPM for Windows to comply with both NHMN and facility (client site) needs.

2. Modify the main menu to make visible reference to the NHMN project and added features.

3. Create special documentation, users' manuals, and technical reference guides for both NHMN and client sites.

4. Adapt MPM screens to closely follow NHMN intake forms
   - General Info, permission, personal history, and health history
   - Technologist intake form
   - Radiologist interpretation form

5. Accept NHMN required data variables, through pop up screens and data codes.

6. Create a comprehensive data interface module that will convert and download MPM data into an acceptable NHMN format.
   - Conversion process will be controlled by user definable table, allowing for modification as NHMN Data requirements change.
   - Radiologist, facility, provider, and other codes will be converted to NHMN codes using translation tables
   - Periodic intervals and activity dates will be user definable
   - Extensive audit trail will be maintained by MPM
   - Data file can be transmitted via disk, modem, tape,... and will contain general audit info.

7. Design the implementation process by which participating sites will be able to utilize MPM and participate in NHMN project without changing daily workflow

8. Customize our initial customer system setup, customization, data entry, and conversion services to match modified system and NHMN project goals.

Notes:
* MPM for Windows is IBM PC, Windows 3.x,95, and NT compatible
* NHMN data will be matched very closely
* Fields in MPM data tables will allow for alternate (NHMN) codes, i.e. rads, site, tech, MD,...
* Facilities will have the ability to modem data files to NHMN
* Download file will contain facility code, dates, # of patients, and other pertinent data for NHMN verification and audit. Download will be able to protect anonymity of patients
* Updates to the MPM system will integrate NHMN customization allowing for easy customer upgrades.
* Insight is licensed by the American College of Radiology to use the Bi-Rads lexicon.
* The MPM system supports the terms and definitions as defined by the NHMN document "Accuracy Definitions and Planned Analyses" dated 10/29/96.

Systems Proposal - Product, Services, and Pricing Overview

I. NHMN Package:

1. **Customization of MPM for Windows:**
   NHMN version as defined above
2. **Supplemental Documentation:**
   special supplements to user's manuals, getting started kits, and technical reference guides for both NHMN and client sites.
3. **Fully functional MPM System for NHMN:**
   license for NHMN research staff usage of MPM for Windows, Non-transferable
4. **2 days of on-site applications with NHMN:**
   testing and integration work with research staff at the NHMN facility, all expenses included
5. **5 full site licenses of MPM for Windows with NHMN modules**
   five single user MPM for Windows systems with NHMN module for full licensure at sites of NHMN's choice, optional modules not included.
6. **Beta site training and installation**
   3 days of "hands on" training at the 2 selected beta sites, one trip, all expenses included
7. **3 upgrades for existing MPM customers in N.H. to customized NHMN version**
   New London, Exeter, and Monadnock, if on annual maintenance
8. **Free upgrade for any future N.H. facility purchasing the MPM system direct from Insight**
9. **12 months of technical support, system updates and modifications.**
10. **28.8K external fax/modem and windows communications software for "on line" support:**

Total Package Price: both option include existing site upgrades

w/ 5 site licenses:	$32,750.00
w/10 site licenses:	$41,750.00
w/20 site licenses:	$57,950.00

II. **Site Licenses:** Each client site will receive the following:

a. The Mammography Patient Manager, single user version w/NHMN module
b. Getting Started Kit and User's Manual w/NHMN supplement
c. System Consultation, Set Up, Customization, and Initial Data Entry
d. Data conversion from existing systems
e. 12 months of technical phone and modem support, from installation date
f. 12 months of system updates, including 1st update, from installation date
g. 28.8K external fax/modem and communications software
h. Guarantee of continued compliance with FDA (MQSA) accreditation and NHMN project requirements

III. **Site Pricing after initial licenses:** applies to facilities in N.H., orders may be placed by NHMN or the facility, prepayment required.

Order qty:			
	1-9	$2,150/ea	(40% discount off published list price of $3,595)
	10 or more	$1,950/ea	(45% discount off published list price of $3,595)

Client Options: (current price)

a. two day on-site training
b. Network module
c. quality control
d. transcription reporting
e. equipment mgmt
f. film tracking
g. HIS / RIS interface
h. extended annual maintenance

- Individual sites may select from any of Insight's options for an additional fee.
- We will extend a 20% discount of std price, for any facility in N. H. independently purchasing MPM.
- Discount structure is applied to established public rates which are guaranteed until July, 1998
- Modifications of NHMN system after the 12 month period will be priced on a per project basis.

Current Price List

I. The Mammography Patient Manager

The MPM system is an easy to use computer software system that will run on any IBM compatible PC or local area network. This innovative and intuitive program is the solution to your breast center's patient management demands. MPM implements an inherently flexible design that allows you to customize the system to meet your unique needs.

1. The MPM software and support services package:

- License to use the single user version of MPM.
- Guarantee of full and continued compliance with FDA and ACR standards.
- Easy-to-read user's manuals with 3½ or 5¼ software diskettes.
- Simple to follow Implementation and Getting Started Kit.
- Consulting services, including assistance with software implementation, hardware configuration, staff requirements, and operations management.
- System setup, customization, and initial data entry.
- Patient data conversion from other software systems.
- Six months of comprehensive customer support services, including system updates, telephone support, and computer modem "on line" assistance.
- ~~14.4~~ 28.8K baud external fax/modem with communications software.

Standard single user system price: $3,595.00

2. System Options: (add on features that may be purchased at any time)

A.	Basic network (multi-user) system: (up to 5 users):	$1,995.00
	10 user version:	$2,995.00
	Unlimited user version:	$3,995.00
B.	Multi-facility module	$ 995.00
C.	Quality control module (processor / unit QC)	$ 500.00
D.	Film Tracking*	$ 995.00
E.	Transcription report generator:*	$ 995.00
	Transcription view station:*	$ 495.00
F.	Windows based report writer with charts and graphs*	$ 995.00
G.	Mobile van module (remote operations and license)	$1,595.00
H.	Interfacing with radiology/hospital information systems:*	$1,595.00
I.	Marketing, equipment mgmt, or inventory control*	$ 995.00 ea
J.	Barcoding Module *	$ 795.00 ea
K.	Multi Site License *	$1,995.00
L.	OmniRad Radiology Information System upgrade *	$1,995.00

* Prices quoted for single-user version of optional modules. For multi-users, call for a quote.

3. Applications Training

A.	Two day, on-site, ASRT approved, 5.5 CE	$1,950 includes expenses
B.	In L.A. offices	$ 600 / day
C.	Two hour "on line" modem training	$ N/C

Systems Proposal - Overview and Acceptance

I. System Price: w/ 5 licenses: $32,750 ; w/ 10 licenses: $41,750 ; w/20 licenses: $57,950

II. Payment Terms:

1. Customization 30% deposit due upon acceptance
   40% due upon completion of Phase 3
   30% upon completion of Phase 5
2. Additional Client Sites Due upon receipt of order from NHMN or client site

III. Implementation:

6 phase approach to project completion. NHMN will submit written approval, analysis, and modifications after every phase. Timetable may vary slightly, due to unforeseen circumstances. Dates based on acceptance of agreement and payment of deposit, prior to March 1, 1997.

✓Phase 1, Mar: Formal submission of forms and data file layouts to Insight by NHMN
Initiation of MPM customization by Insight

Phase 2, June: Completion of initial program development, Schedule beta site installations
⊛ Submission of sample screens, data layouts, and test file for NHMN approval

Phase 3, July: Site visit to NHMN. NHMN's MPM for Windows evaluation system loaded.

Phase 4, Aug: Beta site installation and training, Final system modifications (if any).
1. New London Hospital 2. To be determined

Phase 5, Sept: MPM for Windows with NHMN module ready for distribution to client sites.

Phase 6: ->July 98: On going monitoring, auditing, and system maintenance.

IV. Acceptance:

I have read and understood this proposal and agree to work in good faith with Insight Medical Management Systems to achieve the specified project. Furthermore, I agree that NHMN employees or any related persons will not reproduce, distribute, or sell the MPM system, related materials, disks, technical specifications, and any other privileged information without the written authorization of Insight.

Signature: _____ Date: 2/25/97

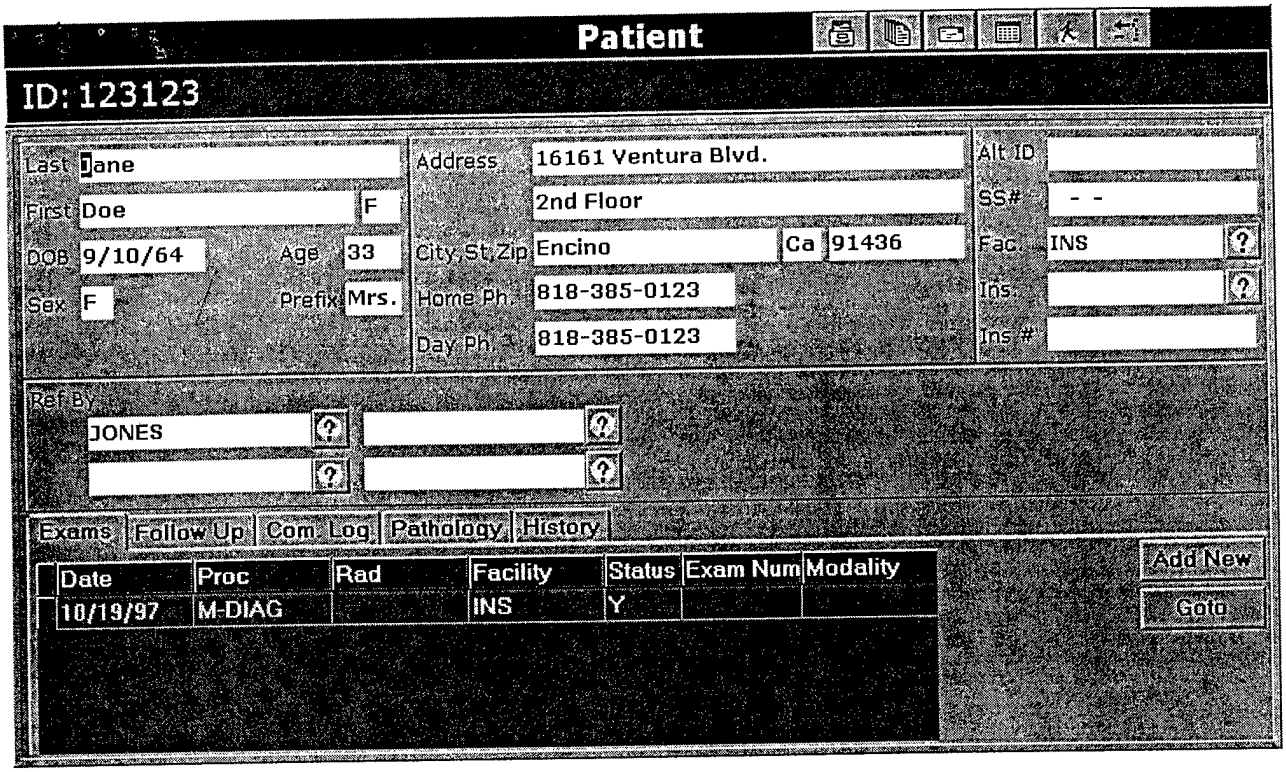
Name: E. Robert Greenberg, M.D. Title: Director

Company: Norris Cotton Cancer Cetner at Dartmouth College

Bill Adr: One Medical Center Drive, Hinman Box 7920

Lebanon, NH 03756-0001

PO#: 241377 Check #: _____ Amount: _____


Patient
ID: 123123
Last Jane
First Doe F
DOB 9/10/64 Age 33
Sex F Prefix Mrs.
Address 16161 Ventura Blvd.
2nd Floor
City,St,Zip Encino Ca 91436
Home Ph. 818-385-0123
Day Ph. 818-385-0123
Alt ID
SS# - -
Fac. INS
Ins.
Ins #
Ref By
JONES
Exams
Follow Up
Com. Log
Pathology
History
Date
Proc
Rad
Facility
Status
Exam Num
Modality
10/19/97
M-DIAG
INS
Y
Add New
Goto

Patient Intake (Tech) form

Patient Has read and Signed NHMN Survey Consent Form
Yes No

Patient Has Had Previous Mammogram
Yes No

Patient Has Breast Concerns
Yes No

Who first became concerned?
Self Partner Physician/Nurse

How Long has there been Concern?

Had Breast Cancer
Yes No Age L R B

Family History of Breast Cancer?
No Yes Unknown

Specify
Mother Sister(s) Daughter(s) Other

How many?

Have Periods stopped permanently?
No Yes Not Sure

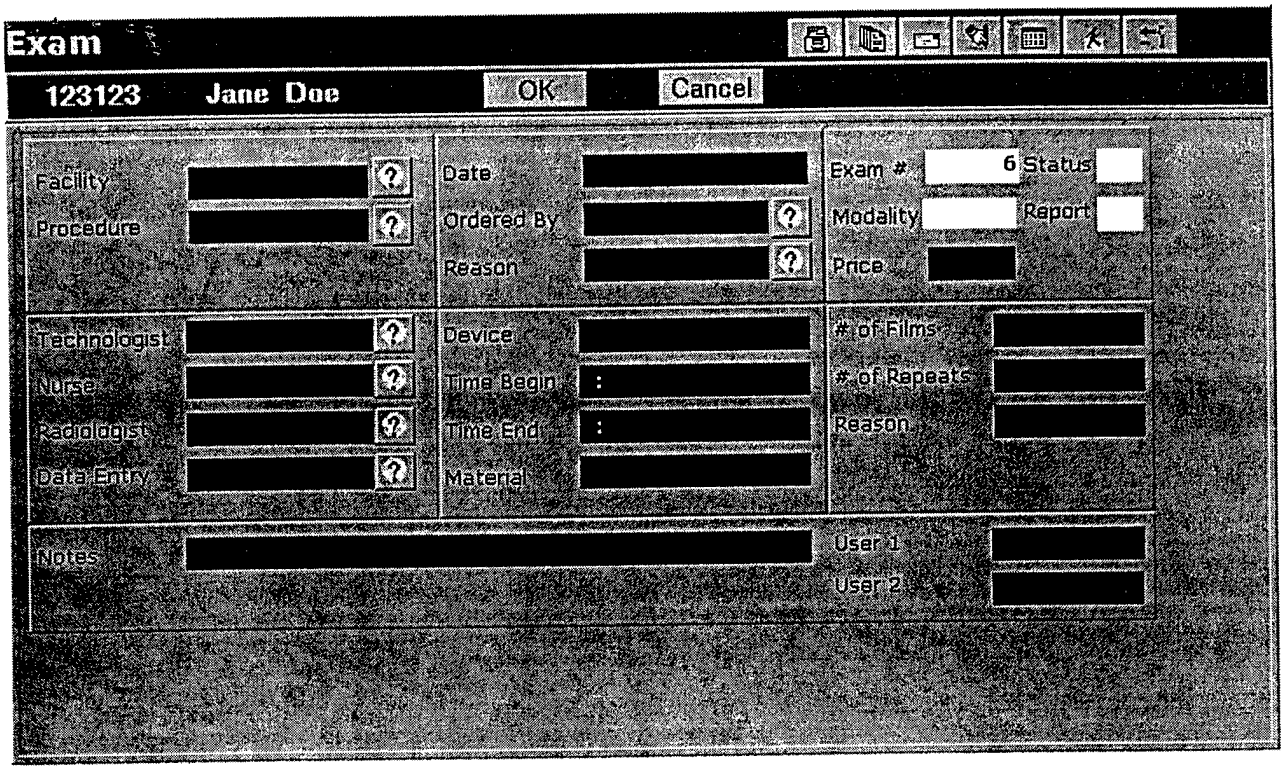
Taking Hormones
Yes No How Long?

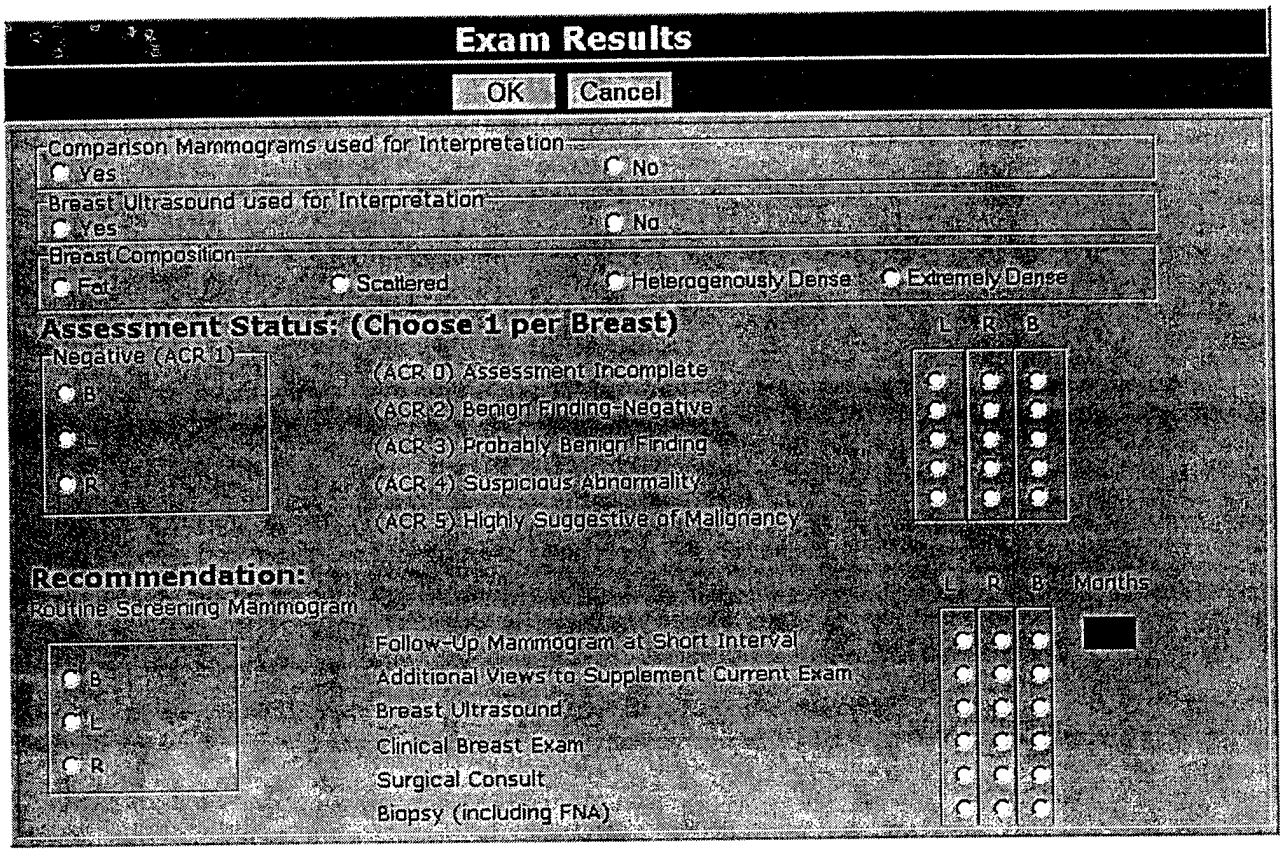
Date Location

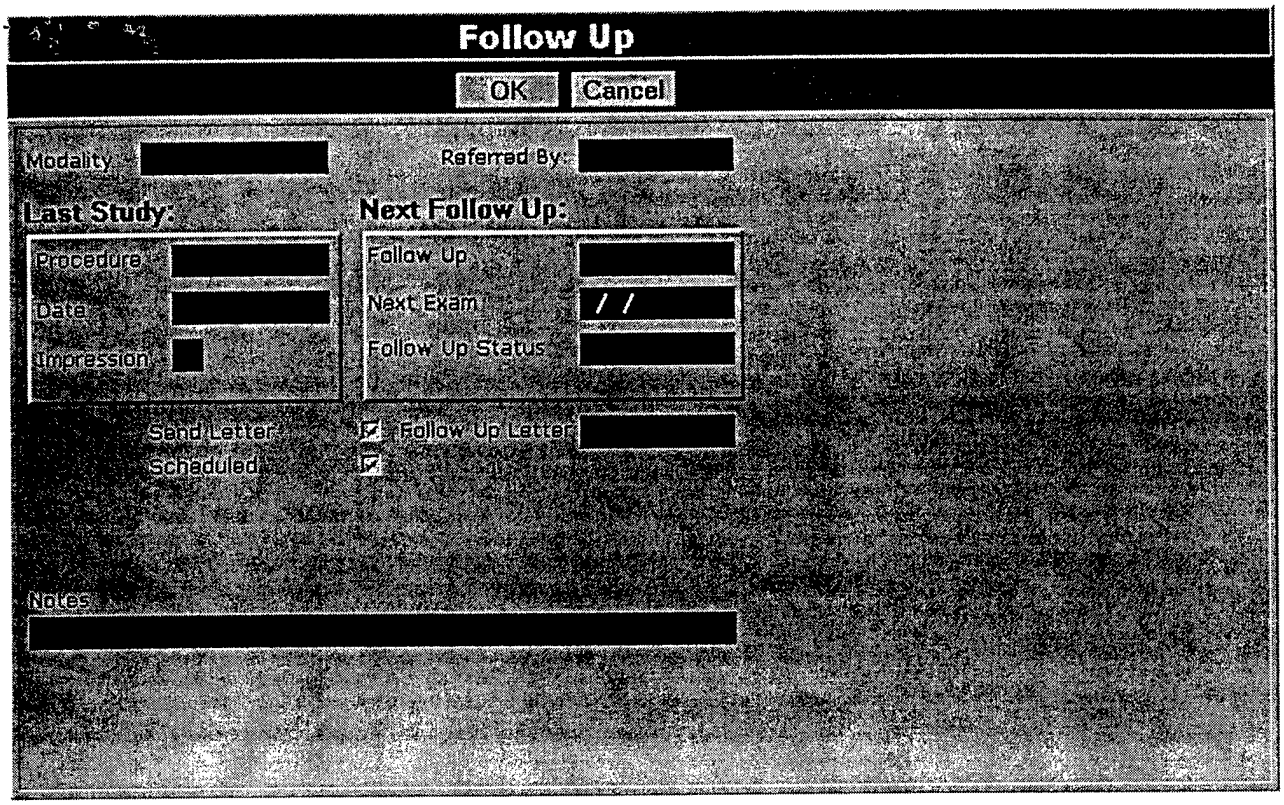
Type of Concern	L	R	B
Lump			
Nipple Discharge			
Skin Changes			
Other (specify)			

Past breast procedures
Yes No

	L	R	B	Date
Breast Reduction				
Breast Implants				
Needle Biopsy				
Surgical Biopsy				
Lumpectomy				
Mastectomy				
Breast Reconstruction				
Radiation Therapy				


Exam
123123 Jane Doe
OK
Cancel
Facility
Procedure
Date
Ordered By
Reason
Exam # 6
Status
Modality
Report
Price
Technologist
Nurse
Radiologist
Data Entry
Device
Time Begin :
Time End :
Material
# of Films
# of Repeats
Reason
Notes
User 1
User 2


Exam Results
OK
Cancel
Comparison Mammograms used for Interpretation
Yes
No
Breast Ultrasound used for Interpretation
Yes
No
Breast Composition
Fat
Scattered
Heterogeneously Dense
Extremely Dense
Assessment Status: (Choose 1 per Breast)
L
R
B
Negative (ACR 1)
B
L
R
(ACR 0) Assessment Incomplete
(ACR 2) Benign Finding-Negative
(ACR 3) Probably Benign Finding
(ACR 4) Suspicious Abnormality
(ACR 5) Highly Suggestive of Malignancy
Recommendation:
L
R
B
Months
Routine Screening Mammogram
B
L
R
Follow-Up Mammogram at Short Interval
Additional Views to Supplement Current Exam
Breast Ultrasound
Clinical Breast Exam
Surgical Consult
Biopsy (including FNA)

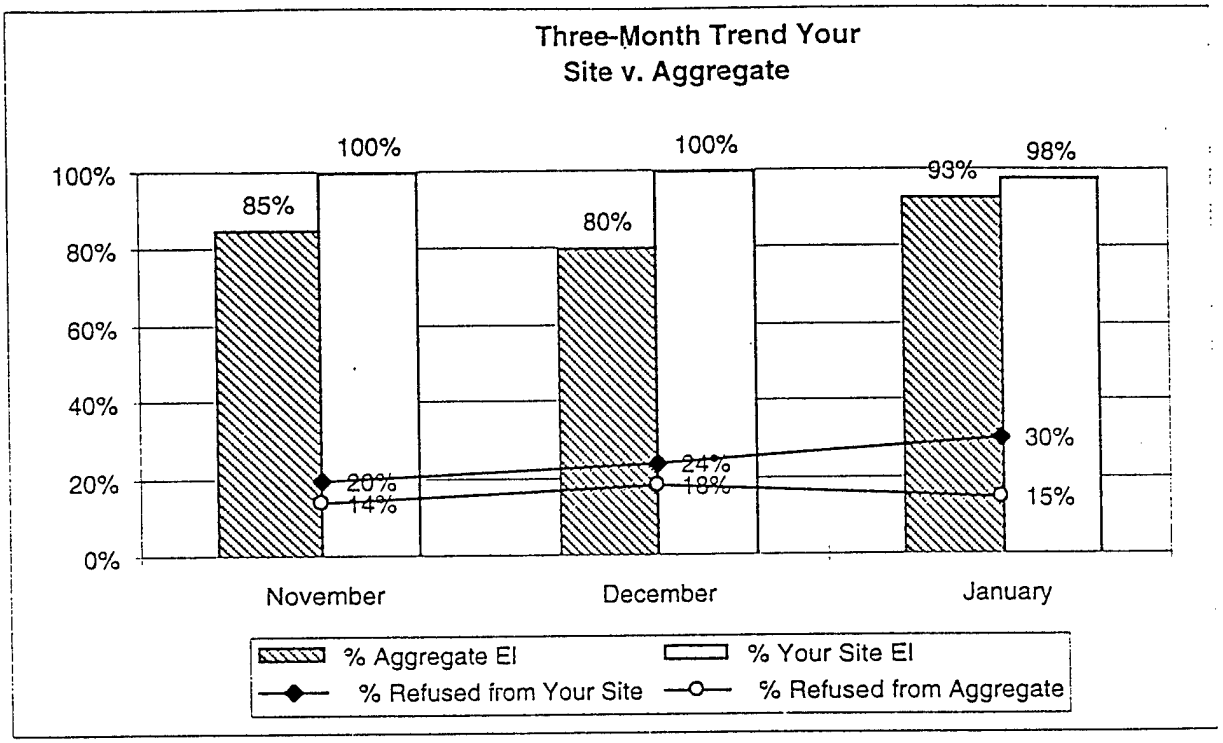

Follow Up
OK
Cancel
Modality:
Referred By:
Last Study:
Procedure:
Date:
Impression:
Next Follow Up:
Follow Up:
Next Exam:
/ /
Follow Up Status:
Send Letter:
Follow Up Letter:
Scheduled:
Notes:

APPENDIX F

Sample Status Report Form (process measures)

Hypothetical Data

STATUS REPORT



Three-Month Trend Your Site v. Aggregate

Total participants registered in the NHMN for this three-month period is 2592. Total participants registered from YOUR SITE for this three month period is 384 This chart indicates a three-month trend in the completeness of the radiologist forms received from your site (lightly shaded bar) compared to the aggregate (striped shaded bar). Also, specific for your site, the chart indicates the percentage of those who declined to participate (connected diamonds).

% Aggregate EI- This represents the essential information present on the radiologist form (indication for the exam, density, assessment, and recommendations) for all site currently participating.

% Your Site EI-This represents the essential information present on the radiologist from (indication for the exam, density, assessment, and recommendations) for your site.

% Refusals from Aggregate-This represents the % of patients forms where the consent was not signed, indicating they refused to participate, from all sites currently participating.

% Refusals from your site- This represents the % of patients forms where the consent was not signed, indicating they refused to participate, from your site.

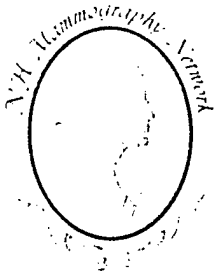
Findings/Recommendations

Of the total participants registered from your site within this three-month period (n=384) we have recorded;

Probably Benign	8
Suspicious Abnormality	3
Highly Suggestive	1
Biopsy Recommendations	1
Diagnostic Mammography	8
Breast Ultrasound	5
Clinical Exam	0

Thank you for your continued effort to ensure the accuracy and completeness of the data. Keith Hamilton Participant Registration Coordinator 650-4148

Hypothetical Data



% Findings and Recommendations by Radiologist

Rad. "1"	
Prob. Benign	3.1%
Susp. Abnorm.	0%
Highly Suggest.	0.0%
Biopsy Rec.	0.0%
Diagnostic Mam.	1.9%
Breast Ultraso.	1.9%
Clinical Exam	0.0%

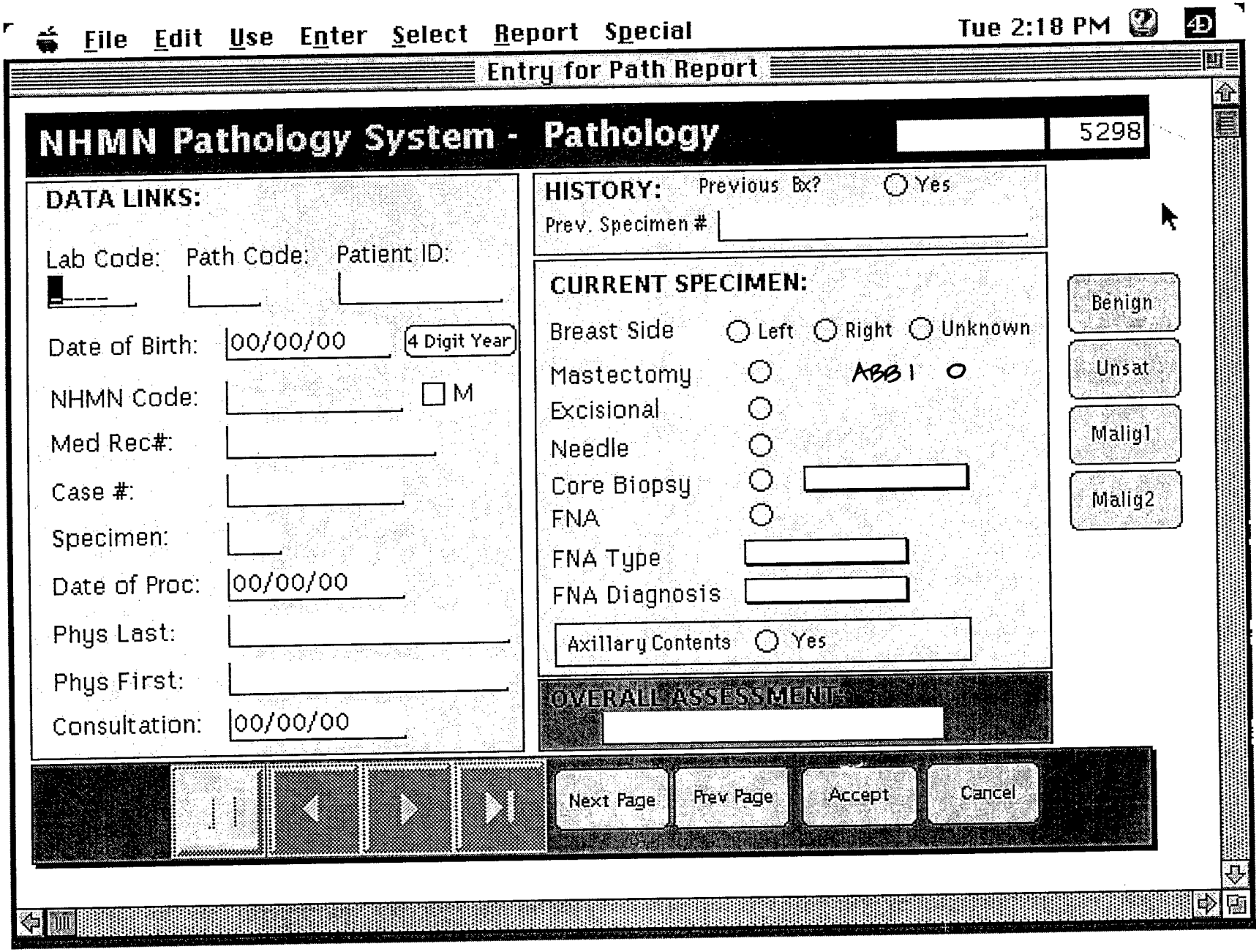
Rad. "2"	
Prob. Benign	0.0%
Susp. Abnorm.	0.0%
Highly Suggest.	0.0%
Biopsy Rec.	0.0%
Diagnostic Mam.	0.0%
Breast Ultraso.	0.0%
Clinical Exam	0.0%
	0.0%

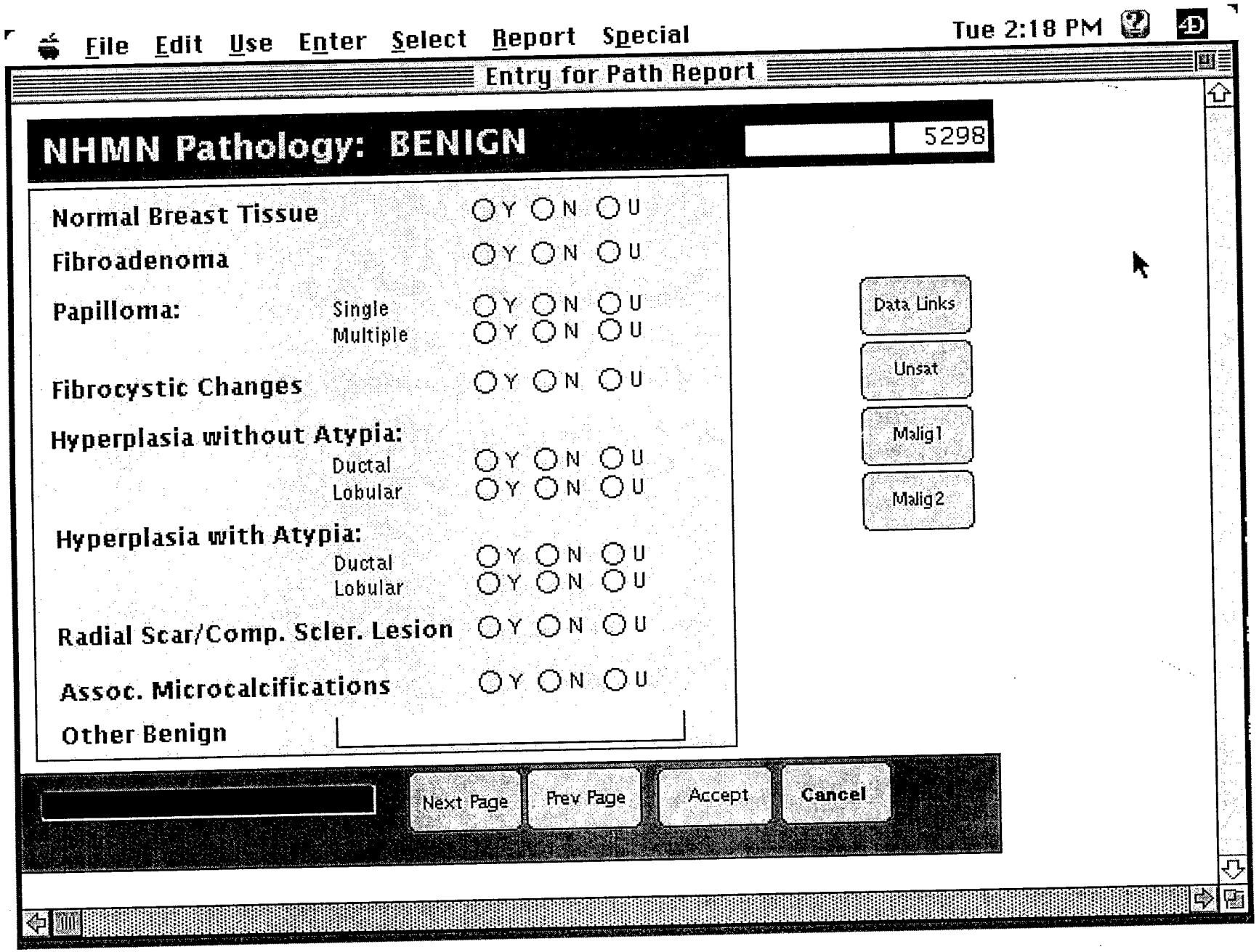
Rad. "3"	
Prob. Benign	4.0%
Susp. Abnorm.	4.0%
Highly Suggest.	>.09%
Biopsy Rec.	2.4%
Diagnostic Mam.	4.0%
Breast Ultraso.	1.6%
Clinical Exam	0.0%

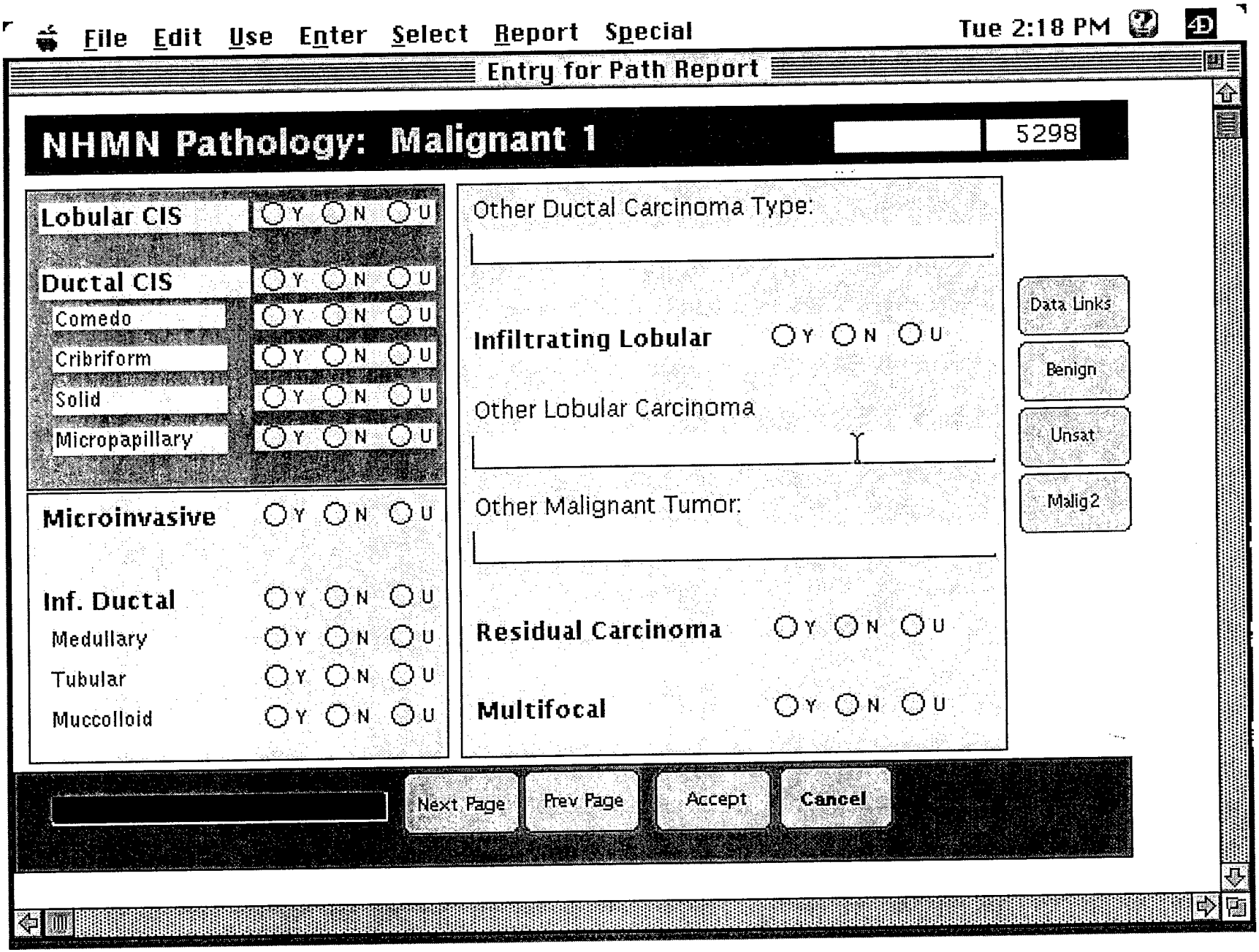
Rad "888"	
Prob. Benign	0.0%
Susp. Abnorm.	0.0%
Highly Suggest.	0.0%
Biopsy Rec.	0.0%
Diagnostic Mam.	0.0%
Breast Ultraso.	0.0%
Clinical Exam	0.0%

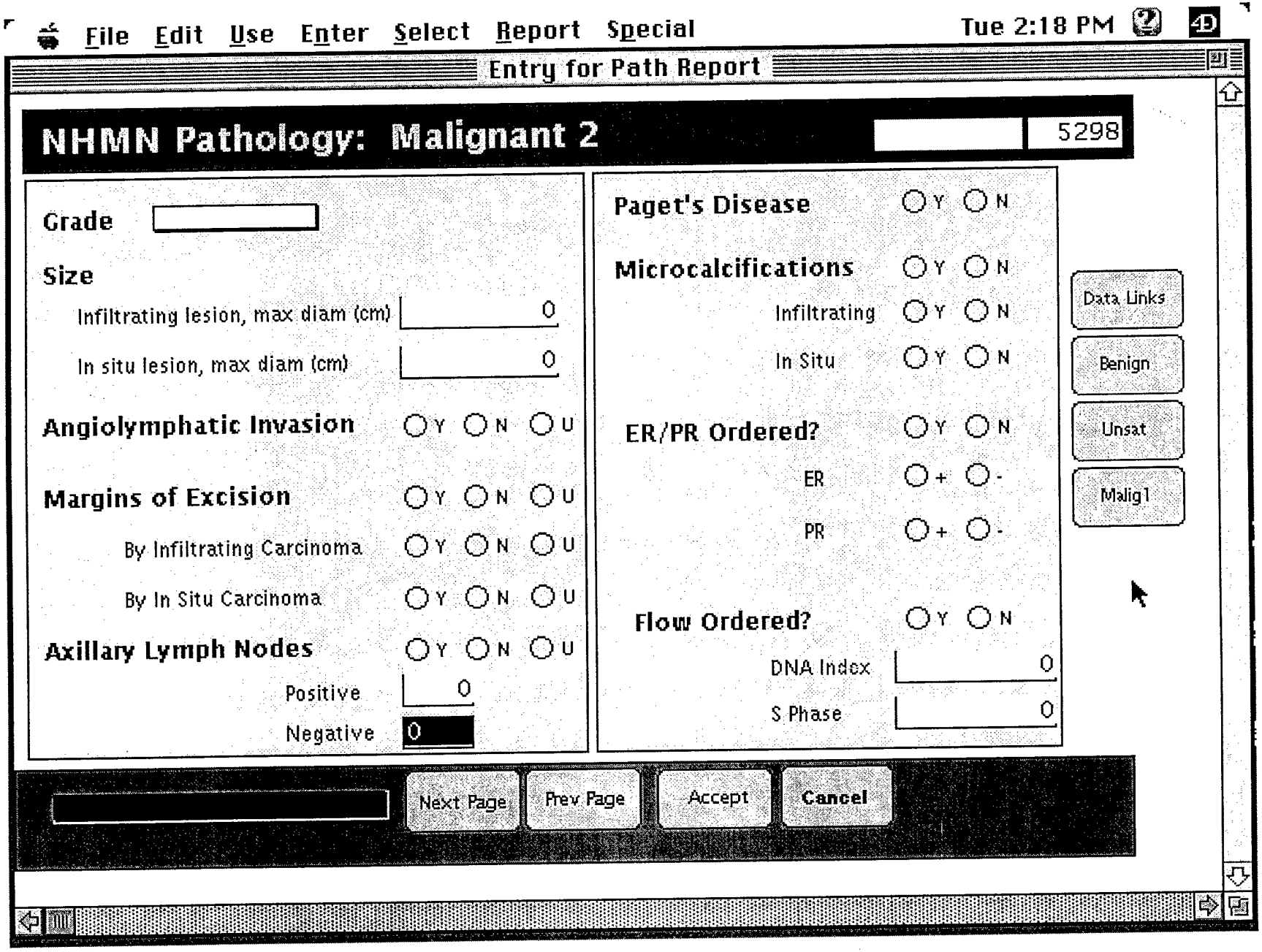
APPENDIX G

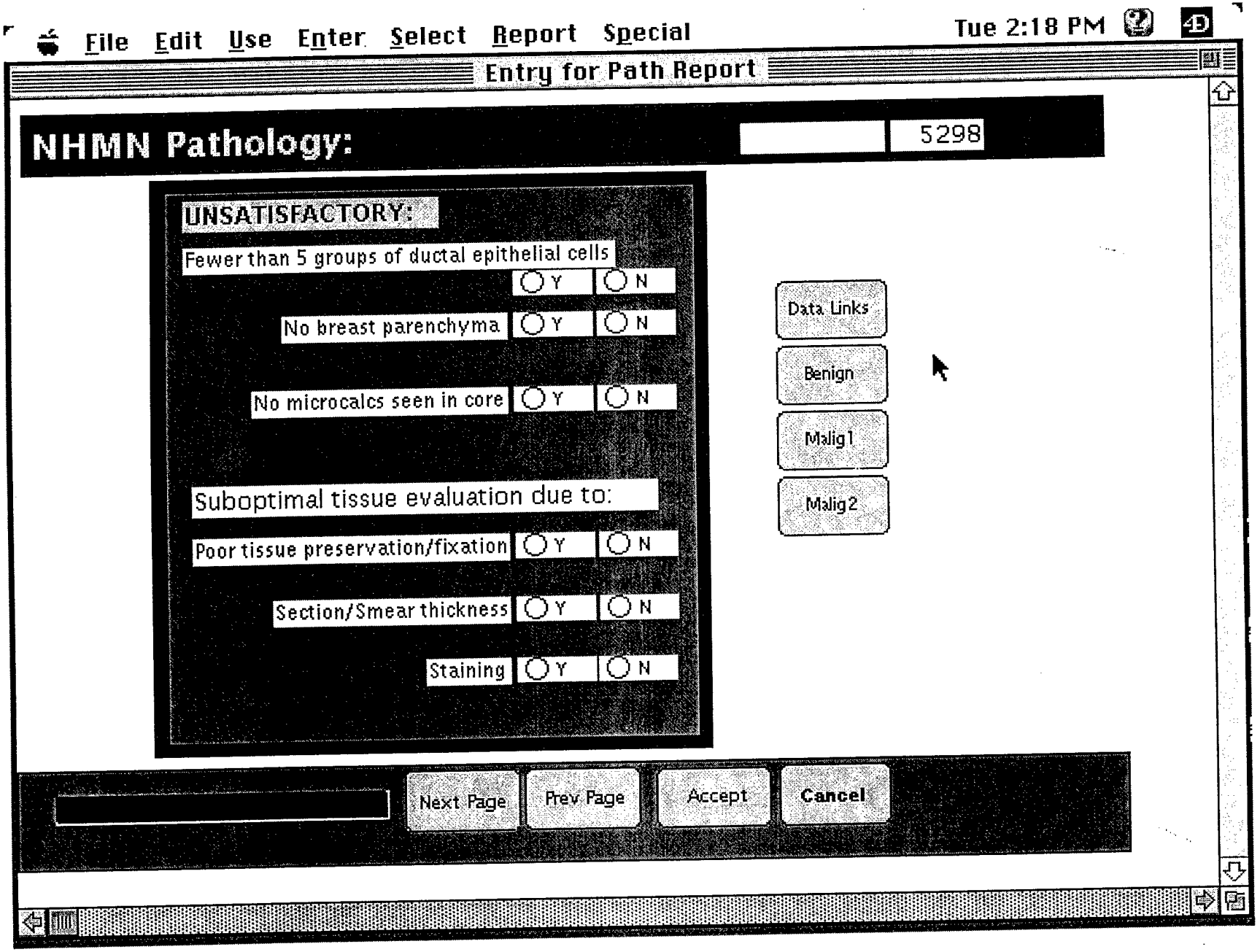
Pathology Interpretation Database Screens


File Edit Use Enter Select Report Special
Tue 2:18 PM
Entry for Path Report
NHMN Pathology System - Pathology
5298
DATA LINKS:
Lab Code:
Path Code:
Patient ID:
Date of Birth:
00/00/00
4 Digit Year
NHMN Code:
M
Med Rec#:
Case #:
Specimen:
Date of Proc:
00/00/00
Phys Last:
Phys First:
Consultation:
00/00/00
HISTORY:
Previous Bx?
Yes
Prev. Specimen #
CURRENT SPECIMEN:
Breast Side
Left
Right
Unknown
Mastectomy
Excisional
Needle
Core Biopsy
FNA
FNA Type
FNA Diagnosis
Axillary Contents
Yes
OVERALL ASSESSMENT:
Benign
Unsat
Malig1
Malig2
Next Page
Prev Page
Accept
Cancel


File Edit Use Enter Select Report Special
Tue 2:18 PM
Entry for Path Report
NHMN Pathology: BENIGN
5298
Normal Breast Tissue
Fibroadenoma
Papilloma:
Single
Multiple
Fibrocystic Changes
Hyperplasia without Atypia:
Ductal
Lobular
Hyperplasia with Atypia:
Ductal
Lobular
Radial Scar/Comp. Scler. Lesion
Assoc. Microcalcifications
Other Benign
Y N U
Data Links
Unsat
Malig1
Malig2
Next Page
Prev Page
Accept
Cancel


File Edit Use Enter Select Report Special
Tue 2:18 PM
Entry for Path Report
NHMN Pathology: Malignant 1
5298
Lobular CIS Y N U
Ductal CIS Y N U
Comedo Y N U
Cribriform Y N U
Solid Y N U
Micropapillary Y N U
Microinvasive Y N U
Inf. Ductal Y N U
Medullary Y N U
Tubular Y N U
Muccolloid Y N U
Other Ductal Carcinoma Type:
Infiltrating Lobular Y N U
Other Lobular Carcinoma
Other Malignant Tumor:
Residual Carcinoma Y N U
Multifocal Y N U
Data Links
Benign
Unsat
Malig2
Next Page
Prev Page
Accept
Cancel


File Edit Use Enter Select Report Special
Tue 2:18 PM
Entry for Path Report
NHMN Pathology: Malignant 2
5298
Grade
Size
Infiltrating lesion, max diam (cm) 0
In situ lesion, max diam (cm) 0
Angiolymphatic Invasion Y N U
Margins of Excision Y N U
By Infiltrating Carcinoma Y N U
By In Situ Carcinoma Y N U
Axillary Lymph Nodes Y N U
Positive 0
Negative 0
Paget's Disease Y N
Microcalcifications Y N
Infiltrating Y N
In Situ Y N
ER/PR Ordered? Y N
ER + -
PR + -
Flow Ordered? Y N
DNA Index 0
S Phase 0
Data Links
Benign
Unsat
Malig1
Next Page
Prev Page
Accept
Cancel


File Edit Use Enter Select Report Special
Tue 2:18 PM
Entry for Path Report
NHMN Pathology:
5298
UNSATISFACTORY:
Fewer than 5 groups of ductal epithelial cells
Y N
No breast parenchyma
Y N
No microcalcs seen in core
Y N
Suboptimal tissue evaluation due to:
Poor tissue preservation/fixation
Y N
Section/Smear thickness
Y N
Staining
Y N
Data Links
Benign
Malig1
Malig2
Next Page
Prev Page
Accept
Cancel

APPENDIX H

Recent Publication about the National Cancer Institute Breast Cancer Surveillance Consortium, which includes the New Hampshire Mammography Network.

Perspective

Breast Cancer Surveillance Consortium: A National Mammography Screening and Outcomes Database

Rachel Ballard-Barbash[1], Stephen H. Taplin[2], Bonnie C. Yankaskas[3], Virginia L. Ernster[4], Robert D. Rosenberg[5], Patricia A. Carney[6], William E. Barlow[2], Berta M. Geller[7], Karla Kerlikowske[4], Brenda K. Edwards[1], Charles F. Lynch[8], Nicole Urban[9], Carole A. Chrvala[10], Charles R. Key[5], Steven P. Poplack[6], John K. Worden[7], Larry G. Kessler[11] for the Breast Cancer Surveillance Consortium

Mammography is the primary method of detecting early stage breast cancer and has been shown in randomized clinical trials to reduce breast cancer mortality, especially among women 50 years old and older [1–5]. Authorities in cancer screening have long recognized that the level of efficacy of screening demonstrated in randomized clinical trials may not pertain to community practice for several reasons [6]. These reasons include possible differences in the population groups receiving screening, lower accuracy of screening mammography in the community, and lower compliance with diagnostic follow-up and treatment in community practice, which may result in more adverse outcomes. Screening effectiveness in community practice today could exceed that estimated in trials because the technical and interpretative quality of mammography has improved since the trials were performed. Furthermore, clinical trial efficacy has been estimated on the basis of assignment to receive screening; to the extent that women assigned to screening were not screened or that women in the control groups were screened, efficacy in trials may have been underestimated.

To optimally evaluate the performance of mammography in a community setting, the screening prevalence and patterns and the associated sensitivity, specificity, and predictive value of mammography in community screening programs should be determined by linkage with cancer outcomes [7, 8]. A program of monitoring should also provide data on specific populations, such as rural and minority subgroups, that are traditionally underserved by screening programs and that may have different breast cancer mortality rates [9]. Before the Mammography Quality Standards Act (MQSA) of 1992, most mammography facilities in the United States did not maintain records that could provide reliable and comprehensive data to evaluate the performance of screening mammography [10]. The concept of a medical audit of outcomes data had been proposed [11] but has not been routinely practiced in the community. The interim regulations of the MQSA mandated maintaining mammography data and performing a medical outcomes audit [12]. In practical terms, the medical audit requirement of the MQSA was limited to an analysis of patients with tests interpreted as "suspicious abnormality" or "highly suggestive for malignancy," which permits evaluation of the positive predictive value of such interpretations. However, the MQSA does not require linkage to population-based cancer registry data or another source of pathology data, without which it is impossible to accurately assess the outcomes of patients with mammograms interpreted as having normal findings. To understand the full effect of

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[8]University of Iowa, College of Medicine, Rm. 2510, Steindler Bldg., Iowa City, IA 52242-1008.

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[11]Food and Drug Administration, 1350 Piccard Dr., HSZ510, Rockville, MD 20850, formerly of the National Cancer Institute.

AJR 1997;169:1001–1008 0361–803X/97/1694–1001

breast cancer screening on cancer outcomes, data on breast cancer screening practices should be linked to data from population-based cancer registries. Moreover, data on pathologic or biologic characteristics of tumors, together with patient demographic and risk factor information, can be linked to population-based registries to better understand staging and survival of patients with mammographically detected compared with non–mammographically detected breast cancers.

Rationale and Research Objectives

A section of the MQSA authorized the secretary of the Department of Health and Human Services to fund research establishing a breast cancer screening surveillance system. In response to this legislative mandate, the National Cancer Institute (NCI) established the Breast Cancer Surveillance Consortium (Appendix 1) in 1994. The three major objectives of the surveillance consortium are to enhance our understanding of breast cancer screening practices in the United States through an assessment of the accuracy, cost, and quality of screening programs and the relation of these practices to changes in breast cancer mortality or other shorter term outcomes, such as stage at diagnosis or survival; to foster collaborative research among surveillance consortium participants to examine issues such as regional and health care system differences in providing screening services and subsequent diagnostic evaluation; and to provide a foundation for conducting clinical and basic science research, especially basic research on biologic mechanisms, that can improve understanding of the natural history of breast cancer. The intent of the last objective is to ensure that a core set of pathologic data on established prognostic indicators is collected and to provide the capability to examine the prognostic potential of other more investigational indicators. The NCI developed a consortium of research sites to address issues that can be adequately examined only in a large sample drawn from diverse geographic and practice settings. The first major effort of the consortium was to create a set of defined variables to facilitate pooling of data with sample sizes sufficient to examine issues in subgroups for which the number of cancers is relatively low, such as younger women, women with a family history of breast cancer, or some ethnic or racial groups.

To address these research objectives, the surveillance consortium is working to develop standardized data collection and linkage mechanisms for mammography practice data and population-based cancer registry data. This linkage can provide cancer characteristics and follow-up of patients for vital status and cause of death and will allow an assessment of the performance of screening mammography in diverse community settings. Furthermore, linking these data will provide a unique opportunity, in the short term, to determine whether differences in the practice of screening mammography and subsequent diagnostic evaluation influence breast cancer detection rates and stage at diagnosis. In the long term, such linked data may have the potential to provide information on whether differences in practice patterns influence breast cancer mortality. Therefore, the surveillance consortium will provide a model for evaluating screening mammography in the United States. It will also yield important information regarding what type of surveillance data requirements are feasible and useful for mammography facilities in the United States to collect and will provide standards of performance for quality assurance.

In the following sections, we present the structure and development of the surveillance consortium; describe the elements and process of data collection and definitions of accuracy and other measures; and discuss procedures followed to assure confidentiality, major areas of analysis, and future directions and uses of these data. We also discuss the challenges in establishing a database that will allow comparison of the performance of screening mammography in diverse health care settings across the United States.

Institutional Review Board approval was obtained for each separate project by the appropriate local board.

Structure and Development of the Surveillance Consortium

In response to the research needs identified by the MQSA, NCI funded several pilot studies at Surveillance, Epidemiology, and End Results Program sites to examine a limited number of feasibility issues, then subsequently funded three other sites in 1994 on the basis of a request for applications issued in 1993. Because data on mammography screening in the potentially underserved minority and rural populations is a priority for NCI, a second request for applications was issued in 1995 that expanded the geographic, rural, and minority representation within the surveillance consortium. Currently the surveillance consortium is comprised of nine sites (Table 1). Eight sites are funded by NCI; of these eight, two sites are funded jointly by NCI and the Department of Defense, and one is funded jointly by NCI and the Centers for Disease Control. One additional site is funded solely by the Department of Defense. Sites are located in most of the major regions of the United States. The first meeting of the surveillance consortium was held in June 1994. Meetings are held every 6 months, and all sites have been participating since October 1995.

This research effort requires a thorough understanding of population-based research and of diverse types and sources of data, including the clinical practice of breast cancer screening, radiology and pathology, and the structure of cancer registries. Because of the diversity of research and clinical expertise required, surveillance consortium investigators include epidemiologists, nurses, internists, family physicians, radiologists, pathologists, statisticians, health educators, health service researchers, economists, and data managers. The scope and depth of the research expertise within the surveillance consortium is substantial and has led to impressive progress in both defining a standard set of variables and prioritizing the research plan.

Data Definitions and Collection

By 2000, the database will contain information on nearly 3.2 million mammographic examinations and over 24,000 cases of breast cancer. The estimated racial and ethnic distribution of women receiving mammography reflects that of the geographic catchment areas for the nine sites (Table 2). The age distribution of women currently receiving mammography within the database is 8%, 31%, 26%, 19%, and 16% for ages less than 40 years, 40–49, 50–59, 60–69, and 70 years and older, respectively. Before beginning data collection, the surveillance consortium identified the critical data elements for evaluating screening performance in diverse community settings, which necessitated consensus on a standard set of major or core data variables (Appendixes 2–4), definitions for analysis, and a standard definition of a screening mammographic examination. Second, standardized codes for each core variable were established. Data from all sites are being evaluated to determine whether similar core data collected from different sources will, in fact, be sufficiently comparable for use in pooled analyses. Third, standard definitions were created for complex outcomes, particularly measures of accuracy such as sensitivity, specificity, and

TABLE 1 Breast Cancer Surveillance Consortium Sites

Site	Metropolitan Status	Yrs of Funding	Funding Source	Women 40 Yrs Old and Older[a]	Estimated Annual Mammograms[b]	Estimated Total Mammograms[c]
University of California, San Francisco	U	1994–2000	NCI	160,916	61,400	200,000
Washington State	U, S, R			528,626		
Group Health Cooperative (and Statistical Coordinating Center)		1994–1999	NCI		41,400	135,000
Fred Hutchinson Cancer Research Center		1994–1999	NCI, DOD		100,000	500,000
Colorado Department of Public Health and Environment	U, S	1994–1999	NCI, CDC	350,641	125,500	643,000
University of New Mexico	S, R	1994–2000	NCI	286,674	100,000	550,000
University of Iowa	S, R	1994–1998	NCI	30,408	10,000	30,000[d]
University of North Carolina at Chapel Hill	S, R	1994–2000	NCI, DOD	366,476	175,000	600,000
University of Vermont	R	1995–2000	NCI	113,700	50,000	230,000
New Hampshire Mammography Network	S, R	1994–1999	DOD	321,277	160,000	275,000
Total				2,055,503	823,300	3,163,000

Note.—U = urban, S = suburban, R = rural, NCI = National Cancer Institute, DOD = Department of Defense, CDC = Centers for Disease Control.

[a] 1990 census.

[b] Estimated annual number of mammograms when sites are fully operational.

TABLE 2 Racial and Ethnic Distribution of Women Receiving Mammography in Breast Cancer Surveillance Consortium Database[a]

Racial or Ethnic Group	Estimated Total Mammograms[b]	Percentage in the Nine Consortium Catchment Areas[c]
White, not Hispanic	2,470,000	78.1
Black, not Hispanic	270,000	8.5
Hispanic	170,000	5.4
Asian and Pacific Islanders	168,000	5.3
Native Americans	29,000	0.9
Other	56,000	1.8
Total	3,163,000	100.0

[a] Assuming no differential in screening rates among racial and ethnic groups.

[b] By 2000.

[c] 1990 census.

positive predictive value. Making these definitions operational must address differences in time to reporting of outcomes by regional cancer registries, cutoffs in the American College of Radiology coding system to categorize findings on a screening mammogram as positive or negative, variations in the use of batch reading, and one- versus multiple-step screening mammography interpretations.

Unlike multicenter clinical trials that use a common protocol and common data collection instruments, the research projects within the surveillance consortium must operate within existing health care systems. Variability in practices at diverse sites presents a challenge to the collaborative research effort for which all sites must collect the same core variables. Core variables are being collected to build three databases that can be linked: patient demographic and health history (Appendix 2), radiologic history (Appendix 3), and follow-up (Appendix 4). Data are being collected from a range of health service delivery systems, including traditional fee-for-service, solo and group radiology practices, managed care organizations, free-standing mammography centers, mobile van programs, hospital-based radiology practices, and nonradiology practices. Data relevant to diagnostic follow-up are also being collected from nonradiology practices, such as surgical practices performing breast biopsies and pathology laboratories. The consortium decided to allow flexibility in data collection of some variables (termed "optional" variables) because of the likelihood that these variables are not readily available at most sites. The following optional variables are being collected at some, but not all, sites: place of birth; number and dates of previous breast biopsies; date of last mammogram; date, number, and outcomes of previous clinical breast examinations; type of and age at menopause; height; weight; whether MR imaging was done; results of clinical breast examinations, sonography, MR imaging, fine-needle aspiration, and core and excisional biopsy; type of biopsy guidance (stereotaxic, sonography-guided, needle-localized); procedure date; and pathology report date. Some of the optional variables, such as pathology report date, have been used in the past to allow more rapid and efficient retrieval of pathology reports or tissue specimens; others, such as weight, are being collected to pursue hypotheses of interest at individual sites.

A central requirement for all sites was linkage of data from mammography centers with pathology data on cancer outcomes from population-based cancer registries. This linkage is accomplished by ensuring that unique identifiers are included in data obtained from each source. Linkage occurs at each site. To ensure anonymity, all study identifiers at individual sites are replaced with unique, anonymous surveillance consortium study identifiers. All sites are linked to population-based cancer registries. Five sites (University of California, San Francisco; two Washington State sites; University of New Mexico; and University of Iowa) are linked to cancer registries within the Surveillance, Epidemiology, and End Results Program. Four sites (Colorado Department of Public Health and Environment, University of North Carolina at Chapel Hill, University of Vermont, and the New Hampshire Mammography Network) are linked to their respective statewide cancer registries. More specific details regarding linkages and cancer registries used at some sites are available from publications from individual sites [13–16].

Although measures of screening performance, such as sensitivity, specificity, and positive and negative predictive value, are commonly applied to evaluate screening, establishing consistent measures across diverse

population-based mammography screening programs is complex. For purposes of analysis, operational definitions were necessary for these performance measures. The surveillance consortium considered analytic methods for consistently converting the five-level American College of Radiology interpretation codes [17] into a dichotomous positive and negative interpretation, appropriate lengths of follow-up time after screening examination to assess cancer status, and histologic coding schemes to establish cancer status. Agreement was reached on several analytic approaches to evaluate the accuracy of screening mammography using both 1- and 2-year follow-up intervals, to alternatively consider mammograms with recommendations for short-term follow-up as positive or negative in separate analyses, and to categorize ductal carcinoma in situ as cancer. Lobular carcinoma in situ will not be categorized as cancer for analyses of performance outcomes but will be evaluated separately. The surveillance consortium will take advantage of the full American College of Radiology scale to determine likelihood ratios for various categories of interpretation and to create receiver operating characteristics for analysis [18]. In receiver-operating-characteristics analyses, regressions will allow for simultaneous adjustment for other factors that may influence accuracy [18].

A second complex issue addressed was the differentiation of screening from diagnostic mammography. Because of incomplete and nonuniform definitions of symptoms, the validity and reliability of data used to classify mammograms as screening or diagnostic have been questioned [13]. The surveillance consortium sought to define data elements that would allow making operational the analytic definition independent of billing codes. Two data elements are used to classify a mammographic examination consistently across sites: symptoms reported by a woman, and whether concern regarding those symptoms was the reason for scheduling a mammographic examination. Mammography performed in asymptomatic women in the absence of concern about a symptom will be classified as a screening examination. When symptoms are reported and mammography is scheduled because of concern for symptoms, the examination will be classified as diagnostic. Finally, in some cases, symptoms may be present but neither the physician nor patient is concerned about these symptoms (as might be the case for a previously evaluated benign breast mass of long-standing duration without recent change in characteristics). In these cases the mammography will be classified as screening in one set of analyses and as diagnostic in another. Analyses by the surveillance consortium based on these definitions should help clarify whether this approach to classifying mammograms as screening or diagnostic alters the assessment of the performance of screening mammograms.

Statistical Coordinating Center

Comparability of variables collected from different sources and with different formats is an important concern. In the fall of 1995, a statistical coordinating center (SCC) was funded as a supplement to the Puget Sound site to assist the surveillance consortium in analyzing data using core variables and to permit comparison of results across all sites. In addition to serving as the repository of data from all sites for pooled data analyses, the SCC serves two major functions for the surveillance consortium: It establishes and evaluates data collection procedures that create comparable definitions and codes for the surveillance consortium's core and optional variables; and it works with sites to develop quality control procedures for data collection, storage, and transmission to the SCC. The SCC will assist in quantifying the short-term outcomes of screening and associated procedures for the surveillance consortium overall and across sites. The SCC is currently evaluating data collection procedures at each site. An immediate result of the evaluation has been a more centralized understanding of which variables can be collected at each site; this understanding has led to a shorter list of primary (core) variables that will be used in pooled data analysis.

Confidentiality

The absence of adequate legislative protection of the data in transit to and while at the SCC was a major issue influencing the ability of the surveillance consortium to perform pooled data analyses. The concern was raised because data contributed to the SCC are exceedingly sensitive. Data from health care providers represent their practice and accuracy in performing mammography; and data from patients pertain to their cancer status, which payers might have interest in obtaining. Although state legislative statutes, institutional quality assurance statutes, or both may (depending on state laws or institutional policies) protect research databases and quality assurance data from either litigation or access, once the data cross state lines or institutional borders they may not be protected. The surveillance consortium addressed this concern by applying for and receiving federal certificates of confidentiality for each member site, including the NCI and the SCC, in accordance with the provisions of section 301(d) of the Public Health Service Act (42 United States Code 241 (d)). The certificate [19] is issued to protect the privacy of research subjects by withholding their identities from all persons not connected with the research. This federal level of protection of surveillance consortium and SCC databases is the highest level of protection available in the United States, and this application of the federal certificate is precedent-setting in that it is the first Public Health Service certificate of confidentiality that has included health care providers as research subjects. The certificates provide protection to research data irrespective of location—whether at the originating site, in transit to the SCC, or at the SCC. Such protection may become increasingly important to the conduct of research involving community practice and patients.

To protect data confidentiality further, common confidentiality procedures are followed. For example, no identifying information is included in the surveillance consortium's shared databases. Under no circumstances will identifiers such as name, address, or Social Security number of specific patients, radiologists, or practices be included in a transferred data set. The identifiers assigned to cases in the database are encrypted. Furthermore, data returned to health care providers regarding accuracy of mammographic interpretation include coded identifiers known only to the individual health care provider. The surveillance consortium is surveying all sites to collect information on quality control practices for maintaining confidentiality of data.

Research Work Groups

In meetings from June 1994 through April 1996, the surveillance consortium delineated three primary areas of research (Table 3) that will use pooled data from all sites. Several secondary areas of research (Table 4) will use data from sites collecting more specific data for particular areas of research. More limited research projects are also occurring at individual sites and include projects focusing on phenotypic and genotypic characteristics of screened breast cancer; mammographic characteristics of benign breast disease; methods to improve the quality of mammographic interpretation; and an assessment of the cost,

TABLE 3 Primary Research Projects in Breast Cancer Surveillance Consortium Using Pooled Data from All Sites

Project	Objective
Accuracy of screening mammography	Examine sensitivity, specificity, and positive and negative predictive values of screening and diagnostic mammography, including variations by region and demographic characteristics
Patterns of care	Examine variations in patterns of care, including follow-up protocols, costs, and the percentage of mammograms with abnormal findings, across facilities by demographic and clinical characteristics and by health care delivery setting
Description of pathologic characteristics in screening-detected cancers	Examine variations in pathologic characteristics of breast tumors (benign and malignant) and in diagnostic breast surgery procedures by demographic and regional characteristics

TABLE 4 Secondary Research Projects in Breast Cancer Surveillance Consortium Using Pooled Data from All Sites

Project	Objective
Effectiveness of feedback mechanisms in enhancing radiologists' performance	Examine feedback to radiologists for quality assurance and medical audits, including how such feedback contributes to standardization
Cost comparisons by region and costs related to diffusion of new technology	Define cost, as opposed to price, data Stratify analyses by different provider and payer settings
Breast density and its relationship to interval cancer risk	Examine the relationship of breast density to mammography performance Compare digitized measures of percent density with radiologist-coded ACR density categories [17]
DCIS risk factors and genetic markers[a]	Examine the accuracy of identifying or coding of DCIS versus invasive breast cancer pathology Compare risk factors for DCIS versus invasive cancer and identify genetic markers for DCIS

Note.—DCIS = ductal carcinoma in situ, ACR = American College of Radiology.
[a] Proposed.

usefulness, and effectiveness of mammography screening. Working groups have been formed to study each of the research areas using pooled data, with mammography accuracy and patterns of care being the focus of initial analyses. In the working group focusing on mammography accuracy, initial analyses will examine regional and demographic variations in accuracy and the effect of changing definitions of measures of accuracy, case status, and duration of follow-up on accuracy parameters. In the working group focusing on patterns of care, initial analyses will examine regional variation in the use of the American College of Radiology lexicon, the usefulness of the short-term follow-up, variation in time to further diagnostic evaluation, and the types of diagnostic evaluations being performed after mammography with abnormal findings.

Summary

The standardized procedures and tools created and tested by the surveillance consortium will be of value to all radiologists in mammography reporting, data collection, and auditing. These tools are particularly important for linking practice data to tumor registry data. Second, because the results and outcomes published by the consortium and its members are based on community practice, they will help establish realistic targets for mammography performance. Finally, these data will give radiologists and referring clinicians more realistic estimates of how mammography will affect their patients.

The surveillance consortium is accomplishing its primary objective of developing standardized data collection and linkage mechanisms for mammography practice and population-based cancer registry data. This database will be a research resource for enhancing understanding of mammography screening practice in the United States and has already fostered substantial collaborative research among its participants. Prospective data collection with the established core variables did not begin at many sites until 1996, and pooled data analysis began in 1997. However, research at individual sites on a range of issues has already been published, is in press, or is under review. Publications have included descriptions of the mechanics of establishing regional and state mammography registries [13–16]; trends in the use of mammography [20, 21]; and evaluation of mammography performance by region and patient characteristics, such as family history and use of hormone replacement therapy [13, 21–24].

In addition to its intended purpose of evaluating population-based screening mammography in the United States, the database will be a valuable resource for future research. With continued collection of data in these populations and follow-up for outcomes, surveillance consortium data will allow assessment of the effect of community mammography screening on the stage distribution of breast cancer. The effectiveness of screening mammograms is hypothesized to vary by biologic characteristics, stage, and rate of growth of breast tumors. Pilot studies within the surveillance consortium are examining this hypothesis and may suggest future research to clarify the associations between biologic characteristics and screening performance. Furthermore, the surveillance consortium database will provide information on demographics, risk factors, and clinical characteristics of and treatment for women who subsequently develop breast cancer. It will provide data on a large population-based sample of women at high risk for breast cancer, including those with family history of breast cancer or benign breast disease. Therefore, this resource may be particularly useful for identifying patients relevant for research into the population prevalence of genetic and other biologic markers for breast cancer risk and for research into the prognosis and potential associations of these markers with other known breast cancer risk

factors. Data from the surveillance consortium will provide estimates of the prevalence of diagnostic follow-up and information relevant to improving the communication of risks and benefits related to screening. The mammography registry may also serve as a resource for intervention trials to study ways to improve screening compliance.

A second use of the database will be to permit the comparison of regional data across the United States. Identifying a uniform set of data to evaluate mammography screening in the population has improved consistency in the process of data collection at the surveillance consortium sites and provides a model for the development of linkages between mammography registries and cancer registries. Other geographic areas, such as states that are establishing mammography registries, have sought information from the surveillance consortium on how to set up comparable systems. Dissemination of such information should foster uniformity in data collection among emerging software packages and at other facilities trying to create linkages between mammography data and cancer registries, thereby further improving the ability to compare the performance of mammography across regions. These efforts should also improve quality of data and, through publication and feedback of the data to radiologists in the community, improve quality of mammography screening. Furthermore, to allow international comparisons, the surveillance consortium is participating in the International Breast Cancer Screening Database project [25], which is seeking to establish a standard set of definitions and classification rules for international comparisons. It is hoped that by developing a common set of data, participants can assess the effectiveness of screening in a variety of practice settings across the United States and internationally.

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APPENDIX 1: Breast Cancer Surveillance Consortium Research Personnel

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Group Health Cooperative

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Fred Hutchinson Cancer Research Center

Nicole Urban, Robyn Anderson, Marianne Drucker, Connie Lehman, Robert Livingston, Dane Moseson, Sue Peacock, Peggy Porter, Mike Tennyson, David Thomas, Emily White, Steve Zeliadt

Colorado Department of Public Health and the Environment

Carole Chrvala (past principal investigator, now at the Food and Drug Administration), Mark Dignan and Gary Cutter (American Medical Center Cancer Research Center, current principal investigator and coprincipal investigator), Ed Hendricks and Tim Byers (University of Colorado), Sharon Michael, John Grevillius, and Victoria Lane

University of New Mexico

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University of Iowa

Charles Lynch, Robert Hartung, Douglas Kelley, Judy McFarlin, Linda Rymars, Michele West, Sue Joslyn

University of North Carolina at Chapel Hill

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University of Vermont

Berta Geller, John Worden, Robert Oppenheimer, Roger Secker-Walker, Martha Harris, Pam Vacek, Donald Weaver, Ruth Mickey

New Hampshire Mammography Network–Norris Cotton Cancer Center

Patricia Carney, Robert Greenberg, Stephen Poplack, Deirdre O'Mahoney, Brenda Berube, Karen Burgess, Scottie Eliasen, Keith Hamilton, Marguerite Stevens, Anna Tosteson, Wendy Wells

APPENDIX 2: Patient Demographic and Health History Data

Demographic Variables

Unique anonymous identification number
Zip code
Date of birth
Race (white, black, Asian or Pacific Islander, Native American, other); ethnicity (Hispanic)
Education (1–11 years, high school graduate, 13–15 years, 16 years, 16+ years)
Health insurance (Medicare, Medicaid, other, none)

Health History

Age at birth of first child (year)
First-degree family history of breast cancer (mother, sister, daughter) and age: <50, ≥ 50
Personal history of breast cancer (yes, no)
Personal history of breast biopsy, surgery, or radiation (yes, no)
Procedure history per breast (implants, needle biopsy, surgical biopsy, lumpectomy, mastectomy, radiation therapy, and reconstruction)

Screening History

Ever screened by mammography (yes, no)
Time since last mammogram (within last year, 1–2 years, 3–4 years, 5 or more years)

Current Health

Menopausal status at examination (pre-, peri-, postmenopausal)
Hormone use at time of examination (yes, no)
Presence of symptoms in last 3 months (nipple discharge or lump; right or left breast)
Reason mammography scheduled (concern regarding symptoms [yes, no])

APPENDIX 3: Radiologic History Data

Radiologic Site and Interpreting Mammographer Identification

Dates of Current Examination and Comparison Film

Use of Comparison Mammogram at Time of Evaluation (yes, no)

Indication for Examination

Asymptomatic patient, screening examination, additional views, short interval follow-up, evaluation of breast problem, diagnostic examination

Type of Examination(s) Performed

Standard screening views, additional views, sonography

Breast Density (American College of Radiology lexicon [17] for breast with highest density)

Entirely fat, scattered fibroglandular densities, heterogeneously dense, extremely dense

Assessment per Woman (American College of Radiology lexicon)

Incomplete assessment (for standard screening views only), normal, normal with benign finding, probably benign, suspicious abnormality, highly suggestive for malignancy

Recommendation

Normal interval follow-up, additional views, sonography, short-term follow-up, fine-needle aspiration, consider biopsy or surgical evaluation, clinical evaluation for further diagnostic evaluation

APPENDIX 4: Follow-Up Data

Follow-Up Performed (summarized per woman)

Date and result (include right versus left breast): additional views, short-interval follow-up mammogram

Date and laterality required, result recorded if available: clinical examination, sonography, fine-needle aspiration, core biopsy, excisional biopsy

Pathologic Variables

Carcinoma pathology (as obtained in Surveillance, Epidemiology, and End Results Program registries)

- Type of procedure, reporting source, laterality
- Staging: size, histopathology, grade, tumor size, number of positive nodes, metastasis present (TNM), American Joint Committee on Cancer stage, extension*, nodal involvement* (number examined and positive), tumor sequence*, estrogen and progesterone receptor status*
- Therapy (date first initiated): surgery, radiation, chemotherapy, hormonal, biologic modification, no surgery reason*
- Follow-up status*: date of last follow-up, vital status last follow-up, cause of death

Benign pathology*

- Type of procedure
- Reporting source
- Laterality
- Histopathology (as recorded and also categorized into major groups: atypical hyperplasia, ductal hyperplasia, fibroadenoma, phyllodes tumor, benign, normal, inconclusive)

Note.—Variables with asterisk are optional for sites using non–Surveillance, Epidemiology, and End Results Program registries.

APPENDIX I

Sample Feedback Charts (outcome measures) and Report Handling Policies

Mammography Summary (LEVEL 1) Report - draft 7/2/97

Facility: _____

Inclusive Dates: _____

I. Volumes:

- Total volume of Mammograms ____
- Total volume of SCREENING mammograms ____
- Total number of DIAGNOSTIC mammograms ____

II.Pathology Outcomes:

Total # Cancers Detected___
Screen Detected (Asymptomatic) Cancers___
Non-Screen Detected Cancers___

PPV-Biopsy Recommended (#cancers diagnosed divided by #affected breasts for which biopsy recommended).

***These results are based on _____ women.**
#Participants (Consenting)_____
#Anonymous (Non Consenting)_____
Pathology outcomes are only available for consenting participants.

III. Patient Level Tracking:

1. Patient Recommended for Biopsy or Surgical Consultation:

Patient Name/D.O.B.	Date(Mam.)	ACR Cat.	Date(Bx.)	Bx. Result
1.				
2.				
3.				
4.				
5.				

2. Patient Recommended for short interval F/U:

Patient Name/D.O.B.	Date(Mam.initial)	(Proj.)Date(f/u mammo)	ACR Cat. f/u
1.			
2.			
3.			
4.			
5.			

3. Patient Recommended for Immediate Evaluation (Cat.0):

Patient Name/D.O.B.	Date(F/UMam.)	ACR Cat.	Date(Bx.)/Bx. Result

1.
2.
3.
4.
5.
.
.
.

4. Patients with Negative Mammogram and Interval Cancer Detected (False Negative):

Patient Name/D.O.B.	Date(Mam.)	ACR Cat.	Date(Bx.)	Bx. Result

1.
2.
3.
4.
5.
.
.
.

** All data provided in this report are based on data submitted by this mammography facility for the time period indicated above.

New Hampshire Mammography Network - LEVEL 2 REPORT
Mammography Report Summary - draft 7/2/97

RESTRICTED USE INDICATED - DO NOT DUPLICATE

- Total # Mammograms:

  Practice_____ Facility_____

  Rad1___ Rad2___ Rad3___ Rad4___ Rad5___
  Rad6___ Rad 7___ Rad8___ Rad9___ Rad10___

- #Biopsies Recommended:

  Practice_____ Facility_____

  Rad1___ Rad2___ Rad3___ Rad4___ Rad5___
  Rad6___ Rad 7___ Rad8___ Rad9___ Rad10___

- #Cancers Detected:

  Practice_____ Facility_____

  Rad1___ Rad2___ Rad3___ Rad4___ Rad5___
  Rad6___ Rad 7___ Rad8___ Rad9___ Rad10___

- #Early (<12months) Follow-Up Recommended:

  Practice_____ Facility_____

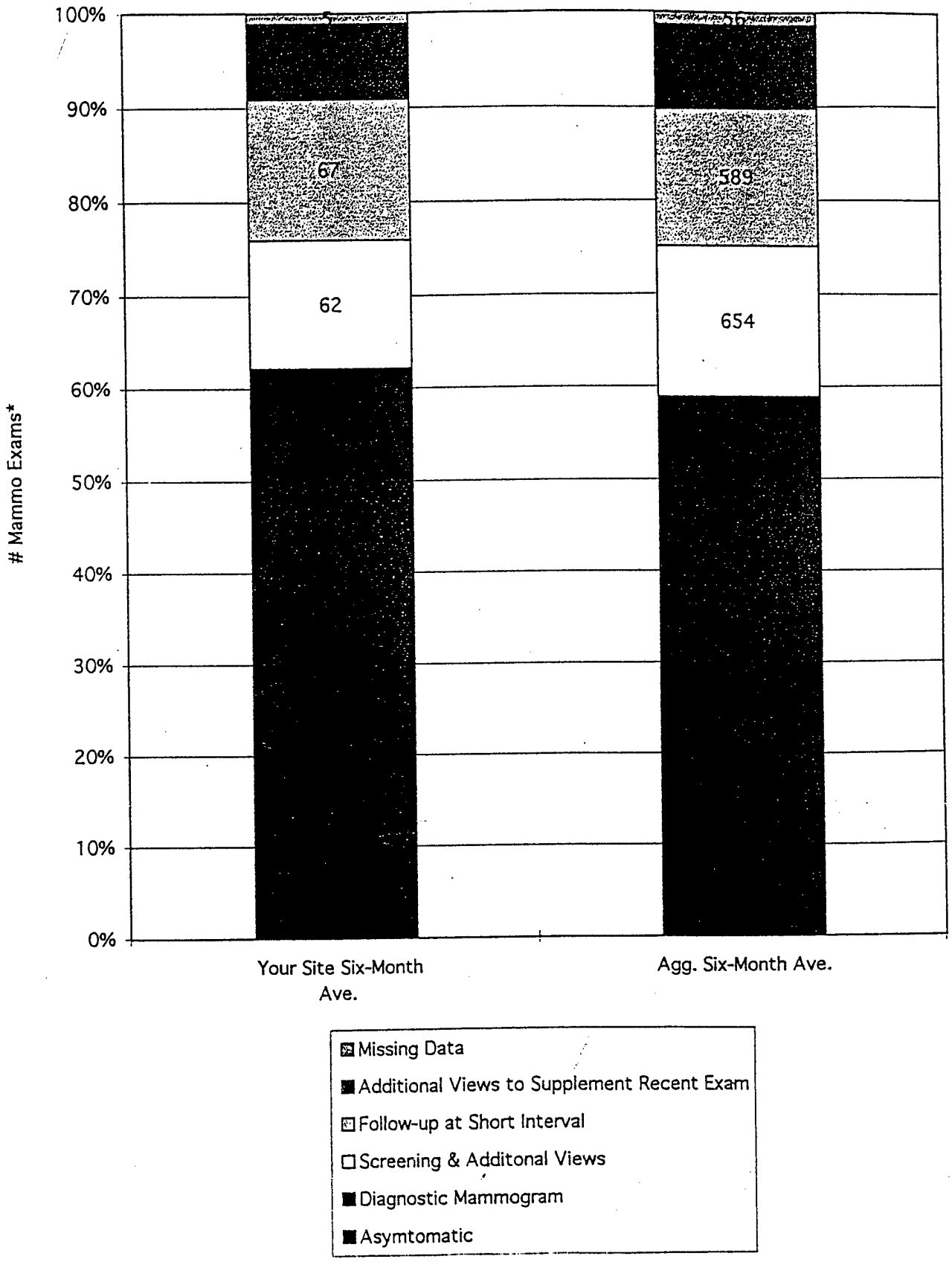
  Rad1___ Rad2___ Rad3___ Rad4___ Rad5___
  Rad6___ Rad 7___ Rad8___ Rad9___ Rad10___

- #Interval Cancers:

  Practice_____ Facility_____

  Rad1___ Rad2___ Rad3___ Rad4___ Rad5___
  Rad6___ Rad 7___ Rad8___ Rad9___ Rad10___

Six-Month Average Volume By Type of Exam
Site_____ v. Agg.

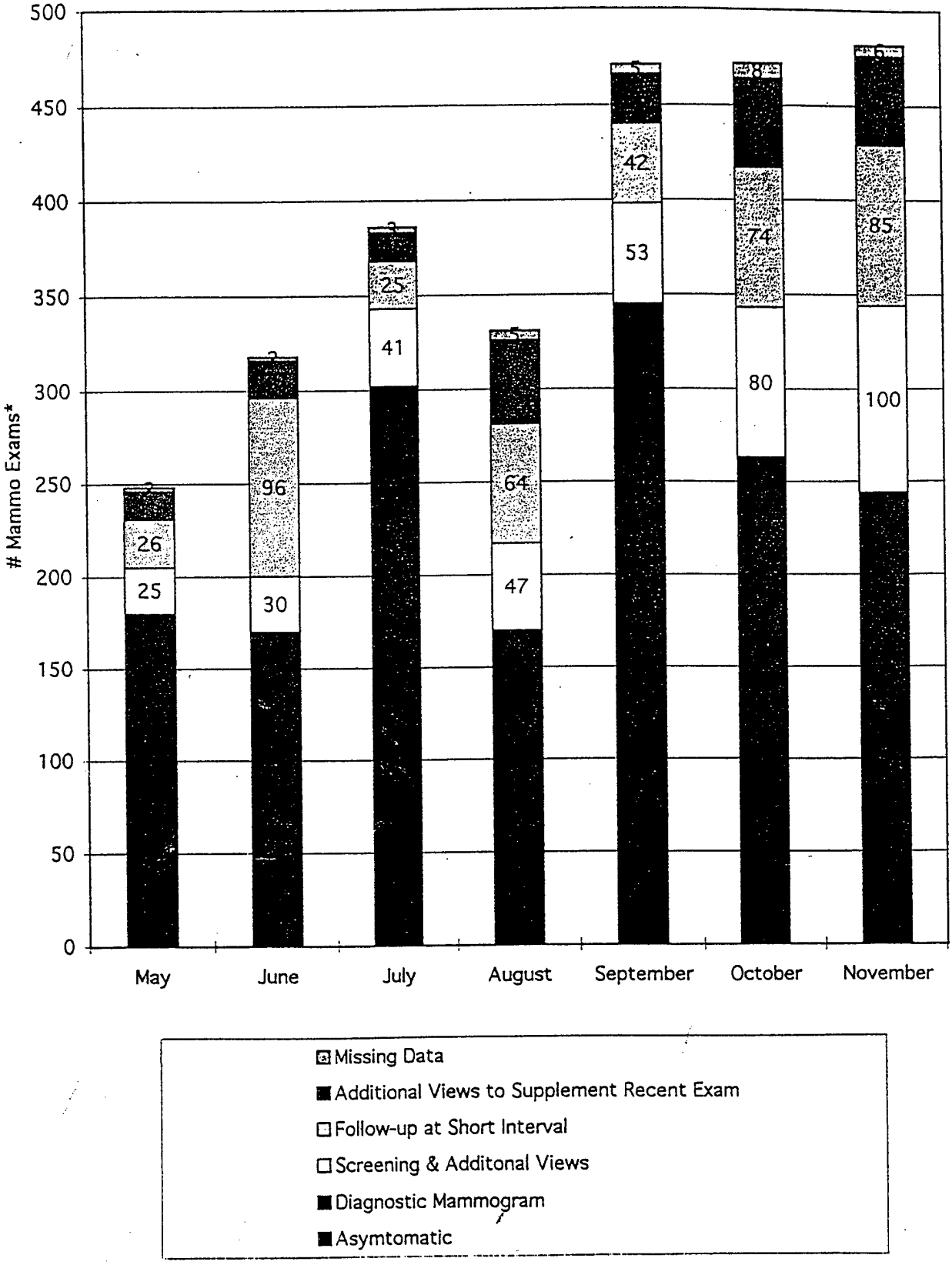


Hypothetical Data
Review for Content Only

*code by most involved breast

KH10/15/96

Monthly Volume by Type of Exam
Site_____



Hypothetical Data
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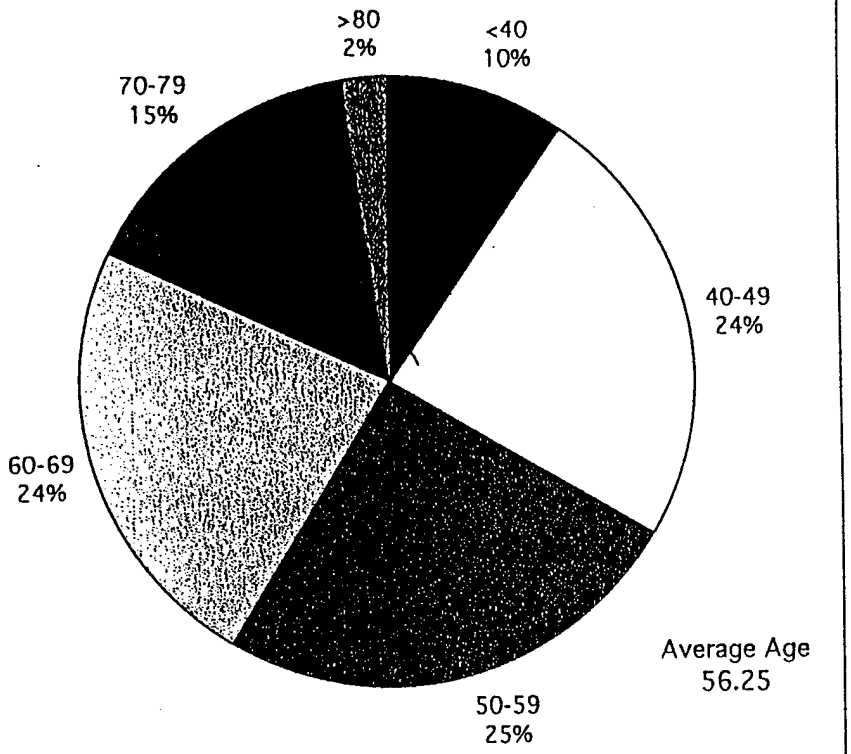
*code by most involved breast

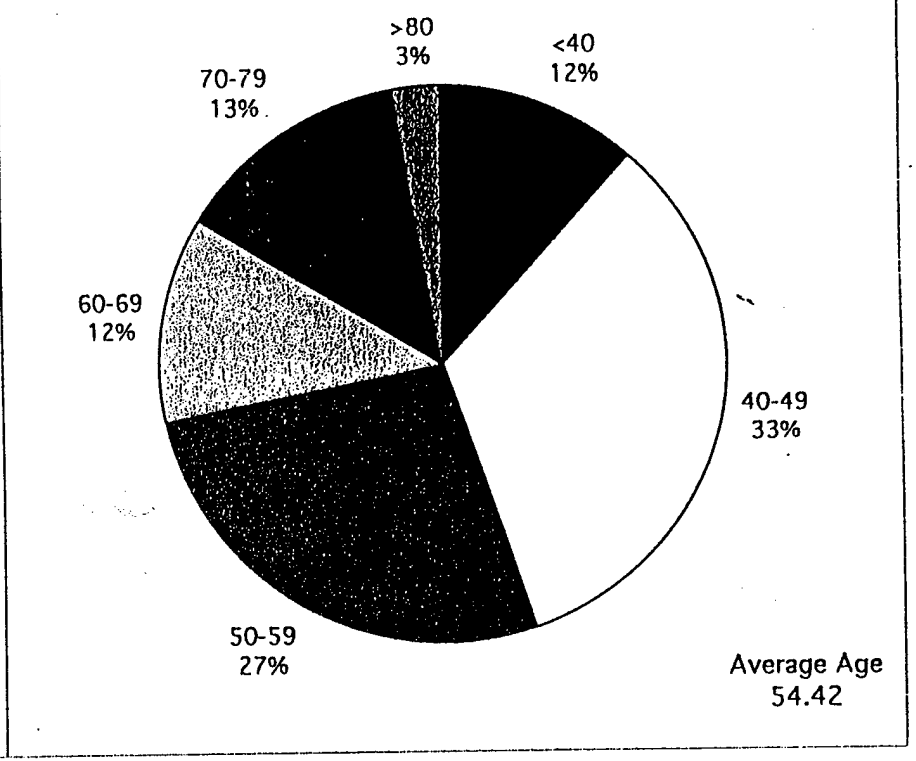
KH10/15/96

Six-Month Age Distribution

Site _____



State Aggregate



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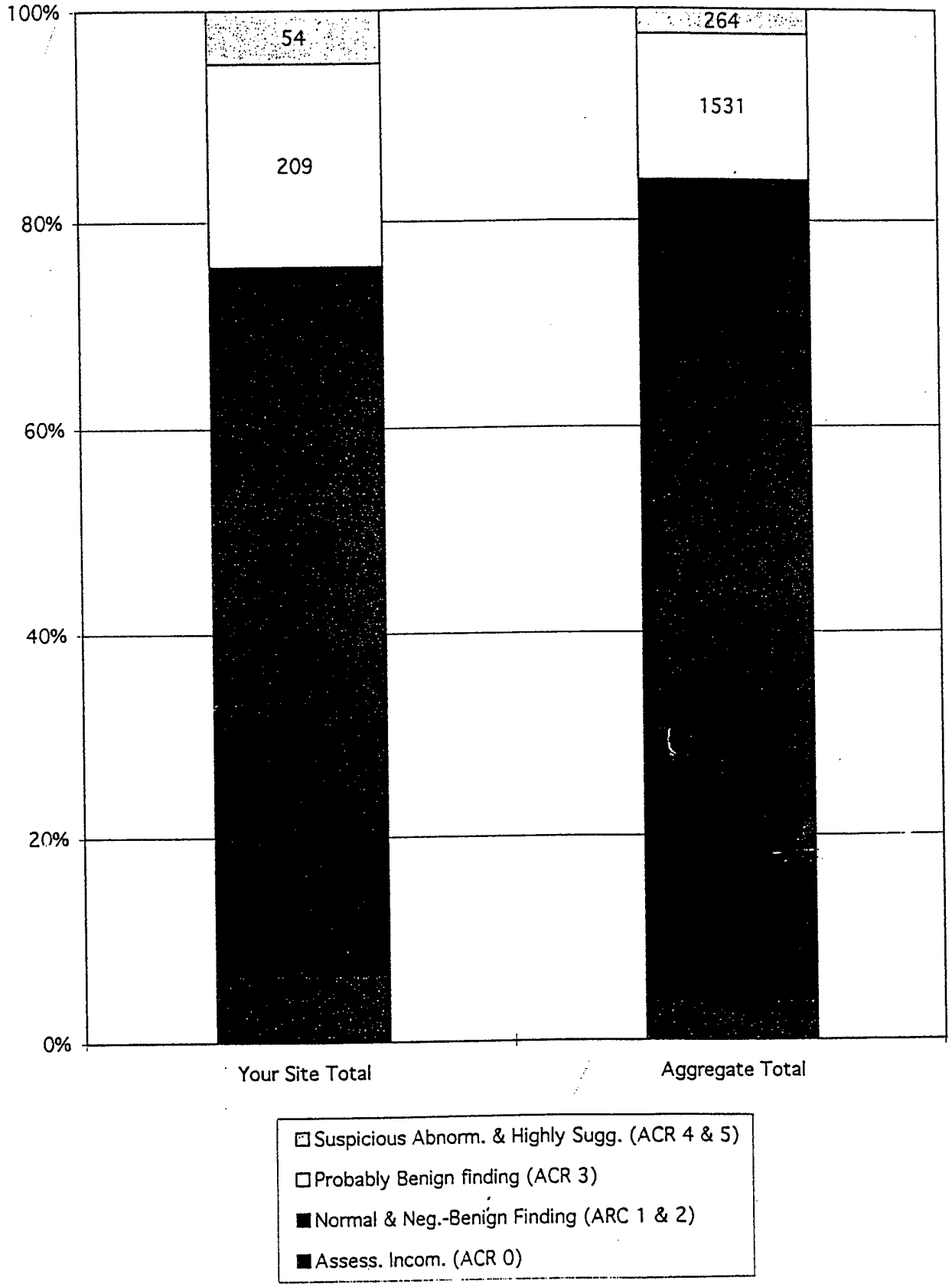
ACR Assessment Status-Site____ v. Aggregate
% and Raw Numbers



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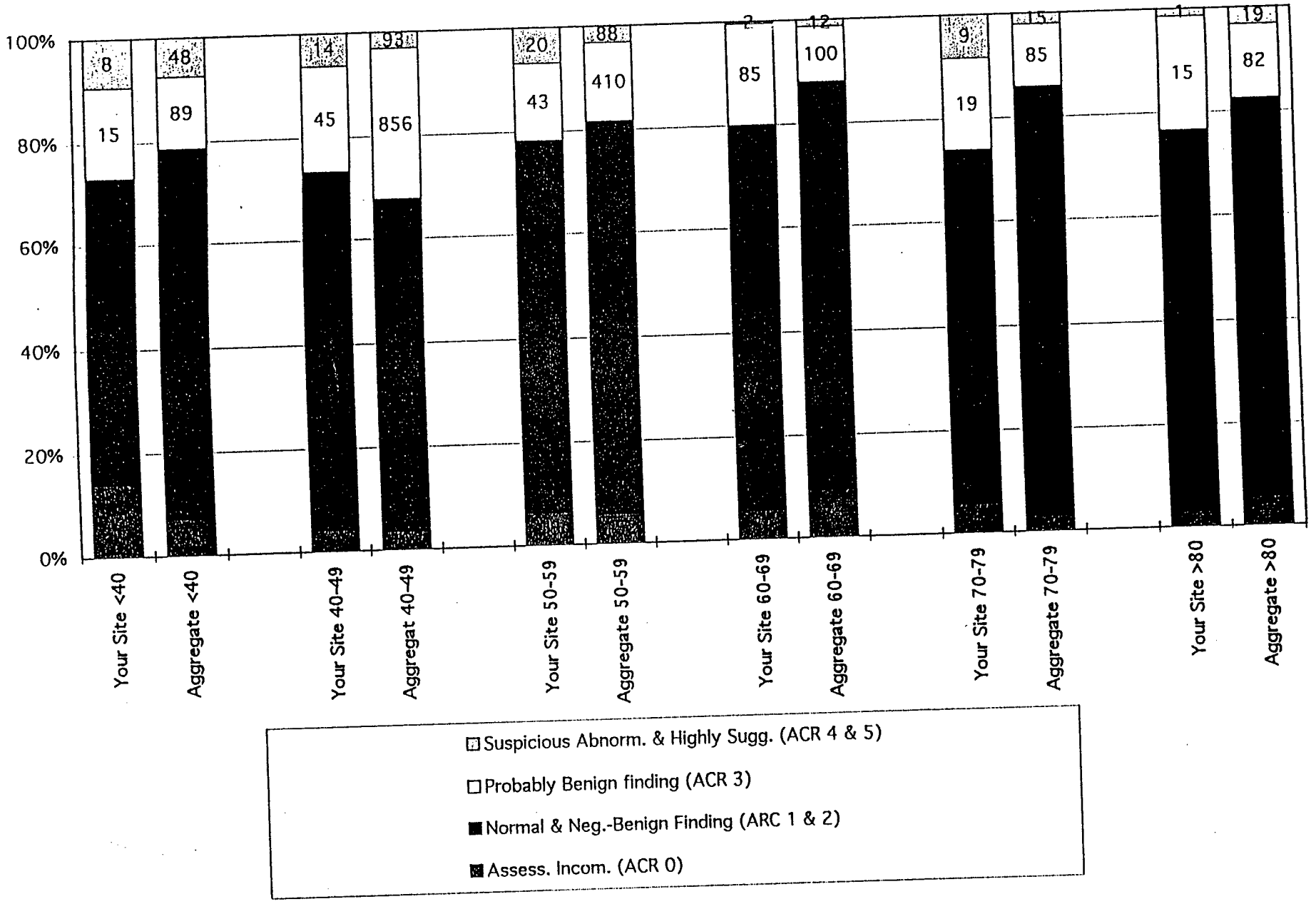
Assessment Status by Patient Age



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Hypothetical Data
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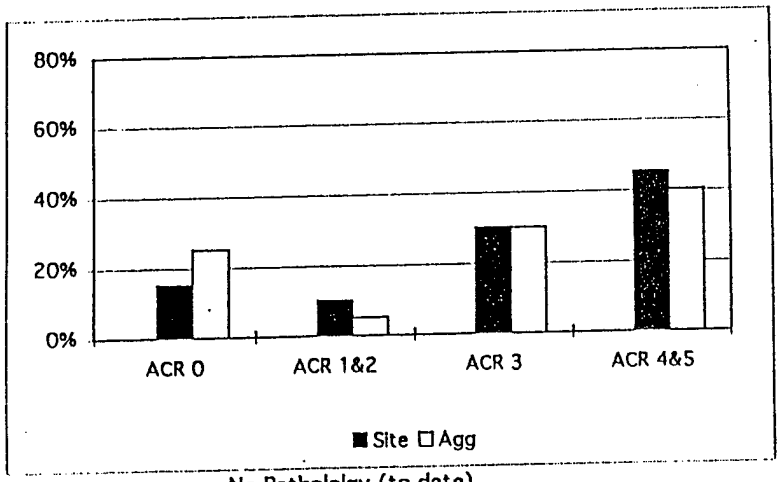
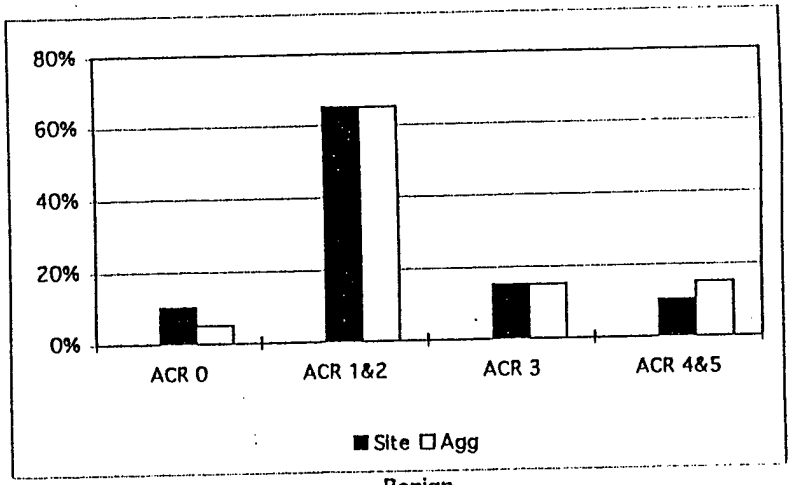
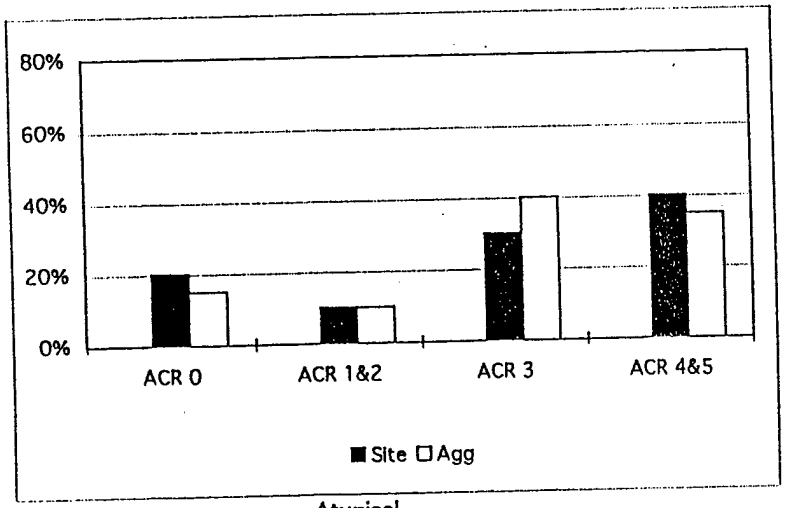
Assessment Frequency by Pathology for Site/State Aggregate



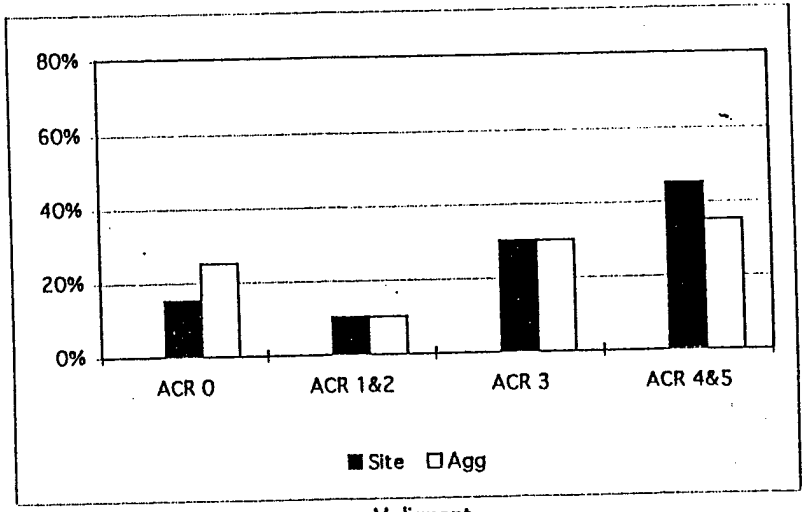
No Pathololgy (to date)



Benign



Atypical



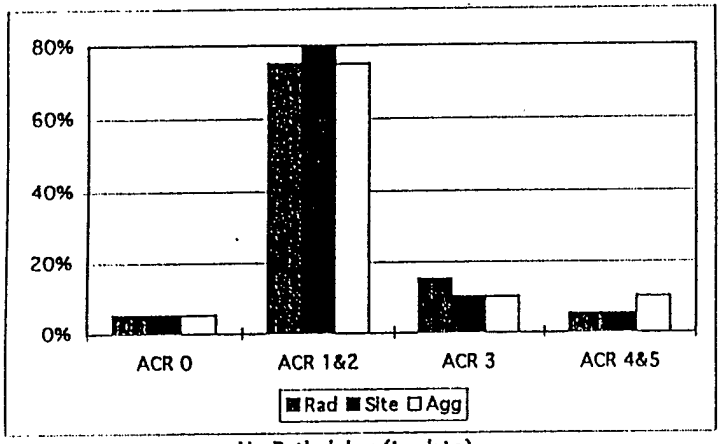
Malignant

	No Pathology (to date)				Benign				Atypical				Malignant			
	Your Site		State Agg.		Site Code		State Agg.		Your Site		State Agg.		Your Site		State Agg.	
	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#
ACR 0	10%	50	5%	80	15%	6	25%	20	20%	8	15%	12	15%	3	25%	25
ACR 1 & 2	65%	325	65%	1040	10%	4	5%	4	10%	4	10%	8	10%	1	10%	10
ACR 3	15%	75	15%	240	30%	12	30%	24	30%	12	40%	30	30%	6	30%	30
ACR 4 & 5	10%	50	15%	240	45%	19	40%	35	40%	16	35%	26	45%	8	35%	35
Total	100%	500	100%	1600	100%	41	100%	83	100%	40	100%	76	100%	18	100%	100

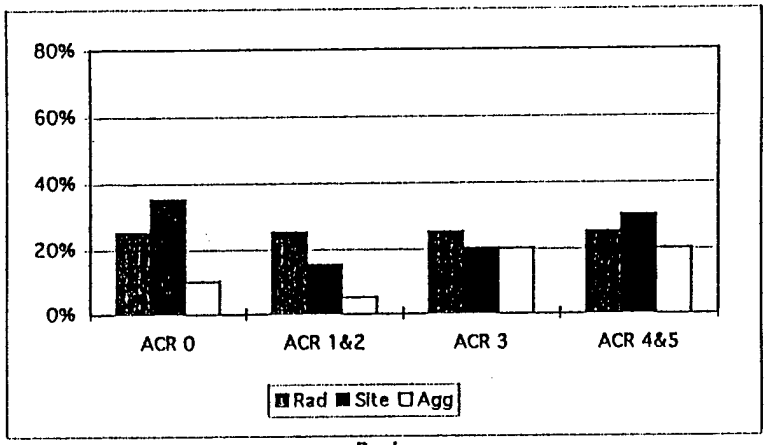
KH10/15/96

Hypothetical Data
Review for Content Only

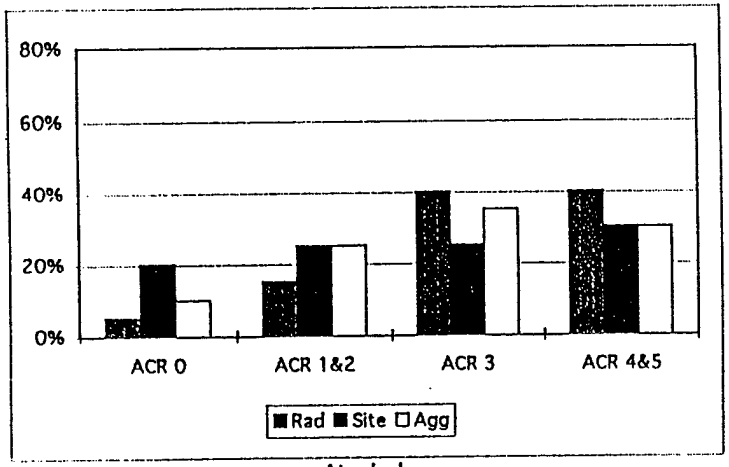
Assessment Frequency by Pathology for Rad/Site/State Aggregate



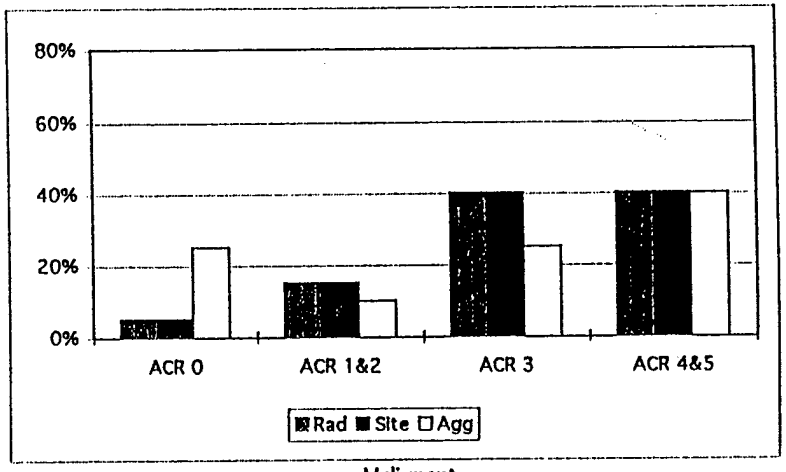
No Patholology (to date)



Benign



Atypical



Malignant

	No Pathology (to date)						Benign						Atypical						Malignant					
	Radiologist		Your Site		State Agg.		Radiologist		Your Site		State Agg.		Radiologist		Your Site		State Agg.		Radiologist		Your Site		State Agg.	
	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#
ACR 0	5%	5	5%	10	5%	100	25%	2	35%	7	10%	8	5%	1	20%	8	10%	15	5%	1	5%	2	25%	25
ACR 1 & 2	75%	75	80%	160	75%	1600	25%	2	15%	3	50%	40	15%	3	25%	10	25%	37	15%	3	15%	6	10%	10
ACR 3	15%	15	10%	20	10%	200	25%	2	20%	4	20%	16	40%	8	25%	10	35%	43	40%	8	40%	16	25%	25
ACR 4 & 5	5%	5	5%	10	10%	100	25%	2	30%	6	20%	16	40%	8	30%	12	30%	35	40%	8	40%	16	40%	40
Total	100%	100	100%	200	100%	2000	100%	8	100%	20	100%	80	100%	20	100%	40	100%	130	100%	20	100%	40	100%	100

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Pathology Results

Site Name

Mammography Results	Malignant (+)	Benign (-)	No Pathology
ACR Assessment 0,3,4,5 (+)			
ACR Assessment 1,2 (-)			

State Aggregate

Mammography Results	Malignant (+)	Benign (-)	No Pathology
ACR Assessment 0,3,4,5 (+)			
ACR Assessment 1,2 (-)			

Mammography Results	Malignant (+)	Benign (-)	No Pathology
ACR Assessment 0,4,5 (+)			
ACR Assessment 1,2,3 (-)			

Mammography Results	Malignant (+)	Benign (-)	No Pathology
ACR Assessment 0,4,5 (+)			
ACR Assessment 1,2,3 (-)			

	Site	State
Sens.*		
Spec.*		
PPV*		
NPV*		

*Assumes data that lacks pathology is benign.

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Patient Results and Outcomes

Biopsy Results

Name	Date of Mammo.	Bx. Results	Date of Biopsy	ACR Code
Belding, Julie	4/5/95	Benign	6/4/95	ACR 0
Fairweather, Sally	5/2/95	Atypical	6/8/95	ACR 3
Galluzo, Jean	6/4/95	Inv.	7/22/95	ACR 3
Hall, Terri	11/15/95	Atypical	12/1/95	ACR 4
Meehan, Pat	12/5/95	DCIS	1/5/96	ACR 3
Webber, Susan	9/5/95	Benign	10/2/95	ACR 1

Biopsy Recommended

Name	Date of Mammo.	Bx. Results	Date of Biopsy	ACR Code
Allen, Carol	4/5/96	Pending	Pending	ACR 5
Davis, Mary	1/23/96	Atypical	3/8/96	ACR 4
Gray, Mary	8/9/95	Benign	11/30/95	ACR 4
Hamilton, Keith	10/4/95	Pending	Pending	ACR 5
Meadows, Linda	11/8/95	DCIS	1/26/96	ACR 4
Roberts, Dawn	2/16/96	Iva. Ca.	4/8/96	ACR 5

Hypothetical Data
Review for Content Only

KH10/15/96

New Hampshire Mammography Network (NHMN)
Report Distribution and Handling Policy
DRAFT 5/28/97

Introduction

All physicians and facilities contributing data to the New Hampshire Mammography Network (NHMN) may receive reports on the mammographic encounters it has provided to the Network. Outlined in this document are the policies for report handling, report development, and data alterations. Two sets of reports will be generated AND MUST BE HANDLED VERY DIFFERENTLY. Level 1 Reports (Summary Reports) will be provided to participating radiologists and mammography facilities for clinical application. Level 2 Reports (Research Reports) will be generated for participating radiologists only? Level 2 reports will contain detailed patient information and mammographic performance data with comparison to the state aggregate. THESE REPORTS MUST BE HANDLED IN ACCORDANCE WITH THIS POLICY. **Reports will NOT be distributed to individuals or facilities where this Report Distribution and Handling Policy has not been signed (see Page 2).**

Internal Report Development and Handling

LEVEL 1 REPORTS will contain clinically useful descriptive information. This report will allow facilities and radiologists to track mammographic volumes, abnormal mammograms for which short follow-up or biopsy was recommended and pathology outcomes. For those sites that choose to supply anonymous data on non-consenting patients this report will include information on this subset of patients as well as consenting women/participants. **Because patient names are included in this report, it must be handled as confidentially as any medical record.**

A two step process will be used to produce these descriptive reports. One NHMN staff will generate them and a second will place them in specially coded envelopes, which will then be added to the appropriate envelope for the facility to which the mailing will be sent.

LEVEL 2 REPORTS generated by NHMN staff will contain performance data and therefore will NOT identity the mammography facility or radiologists. Dummy codes will be generated for NHMN on-site handling. A new dummy code will be generated for each new set of reports so that facilities'/radiologists' performances cannot be tracked over time. The dummy codes shall never be linked to the participating radiologist or facility study identifier.

We will use a two step process for generating reports, where two different individuals are responsible for report generation and on-site handling. One person will be kept blind to the dummy code, but will have access to the database for report production and the other will be kept blind to the data source, but will apply the dummy code for processing and ultimate mailing.

Level 2 Reports must be handled with the strictest confidentiality possible (in accordance with Institutional Review Board for the protection of human subjects). For all Level 2 Reports that include comparative data, all radiologist/facility data will be reported in sufficient aggregate to minimize the risk of identifying individuals, radiology practices or mammography facilities, unless otherwise requested from the facility or radiology practice (ALL radiologists in the group must agree to receive data with small cell sizes if this information is to be included). Thus, any cells that have a small number of cases (which may identify an individual or a facility) shall be suppressed in those reports, other than those noted above.

Report Handling by Participating Radiologists and Facilities

Reports will be generated at six month intervals (January 1 and July 1). They will be delivered to each mammography facility by the field coordinator assigned to that facility or will be sent by express or certified mail. Allowable uses of reports include:

- Level 1 Reports - **CLINICAL SUMMARY REPORTS**

These reports are designed to facilitate practice management and patient tracking and to help fulfill MQSA audit requirements. They may be kept on file at mammography facilities according to the radiologist and facility's wishes.

- Level 2 Reports - **RESEARCH REPORTS**

These reports identify both facilities and providers and are identifiable sources of performance outcome measures. **These reports must be handled VERY CAREFULLY. They are ONLY to be reviewed by the individual (s) or groups who receive them.**

Inappropriate uses of reports include:

- Any media or marketing campaigns that use NHMN data for advertising, recruitment of patients, or other avenues of public information.

- Any sharing of reports with individuals not related to your professional practice or facility administration. (Level 2 reports should only be viewed by participating radiologists).

- Use of Level 2 data to satisfy professional credentialing.

- **LEVEL 2 REPORTS SHOULD NOT BE DUPLICATED**

We are currently protecting the database from possible litigation with a NH State Statute authorized by the NH State Health Commissioner and a Federal Certificate of Confidentiality. This protection is afforded because the database is a

RESEARCH database. If data are used for non research purposes (as outlined above) this may threaten the protection now afforded.

After your Level 2 Reports have been reviewed by all appropriate parties, we ask that you return them to your NHMN field coordinator. We will shred the paper reports once they have been returned to our office. We will keep a computer disk that contains reports in a safety deposit box off-site. The safety deposit box will only be accessed after a request for access has been accepted by a majority of the advisory committee (of community radiologists). Access will be limited to a single designated NHMN staff member following authorization by a community radiologist representative of the NHMN Steering Committee. Newly generated reports will be shared only with the individual making the request. **We ask that you not make photocopies, as this may pose a disclosure risk.**

Data Alteration Policy

It is the goal of the NHMN registry staff to provide you with the most accurate reports possible. Because of patient consent issues, not every mammogram performed at your institution will be included in your report. We will do our utmost to generate accurate data on clinical performance. We understand that errors in data entry or administrative handling issues may occur on rare occasions, and thus have developed a policy on data alteration:

Data submitted to the database will be altered after a report has been generated ONLY if the facility or radiologist/pathologist can illustrate, using clear documentation, that an entry or other administrative error was made.

Agreement Statement

I have read and understand the contents of this policy. I agree to handle NHMN data reports as outlined.

_____	_____	_____
Signature	Date	Name (please print)
_____	_____	_____
Witness's Signature	Date	Name (please print)